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Background

In the United States, Federal and State government agencies ensure the safety of animal feed[1]. The Food and Drug Administration (FDA) is responsible for ensuring that all foods and feeds moving in interstate commerce, except those under the United States Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. State agencies are responsible for conducting inspections and regulatory activities that help ensure food and feed produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. State agencies primarily perform inspections under their own regulatory authority. Some State agencies conduct inspections of feed facilities under contract with the FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect animal feed. To better facilitate a partnership among regulatory authorities, regulatory programs should be equivalent in effect.

Maximizing resources between FDA and the States supports the ongoing work of the Partnership for Food Protection (PFP) to develop an Integrated Food Safety System (IFSS). The FDA and the Association of American Feed Control Officials (AAFCO) are members of the PFP. The draft vision for an IFSS was developed in 2009[2]. One of the foundational principles of an IFSS is the implementation and uniform application of model standards so that Federal, State, territorial, tribal, and local regulatory agencies conduct inspections under the same set of standards. The Voluntary National Retail Food Regulatory Program Standards (VNRFRPS) and the Manufactured Food Regulatory Program Standards (MFRPS) are examples of such model standards. However, the VNRFRPS and MFRPS were developed for human food only and do not apply to animal feed. As further development on the IFSS progressed, there was a recognized need to develop standards for animal feed regulatory programs. One of the key recommendations that came from the 2010 50-State workshop ("A United Approach to Public Health") was the development of standards for animal feed regulatory programs. Standards provide a consistent, underlying foundation that is critical for uniformity across State and Federal agencies to ensure the credibility of all programs under an IFSS.

The Food Safety Modernization Act (FSMA) provides further support for developing Animal Feed Regulatory Program Standards (AFRPS). FSMA was signed into law in January 2011 and calls for enhanced partnerships and integration with Federal, State, local, tribal, and territorial partners. The enhanced partnerships and integration called for by FSMA will allow FDA to rely on inspections and data collected by other agencies to support regulatory activities and further the idea of an IFSS.

In 2011, FDA and AAFCO entered into a partnership to develop the AFRPS. These standards are designed to promote uniformity and consistency among animal feed regulatory programs. This is consistent with the principles of the FSMA and the fundamental goal of AAFCO and FDA to provide a mechanism for developing and implementing uniform and equitable statutes, regulations, and standards to enhance the protection of the nation's animal feed supply.

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[1] "Food" is defined in section 201(f) of the Federal Food, Drug and Cosmetic Act (FD&C Act) in part as articles used for food for animals and articles used for components of such articles. In addition, section 201(w) of the FD&C Act defines "animal feed" as "an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal." The AAFCO Official Publication (OP), 2011 utilizes essentially the same definition of the term "animal feed." For purposes of this document, the term "animal feed" (henceforward referred to as "feed") is used to represent the definitions in FD&C Act sections 201(f), 201(w) and the AAFCO OP, and is inclusive of feed for food-producing animals and pets.

[2] The draft vision is discussed in "Establishing a Fully Integrated National Food Safety System with Strengthened Inspection, Laboratory, and Response Capacity," which is available online at http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/UCM183650.pdf

Introduction

The Animal Feed Regulatory Program Standards (AFRPS) establish a uniform foundation for the design and management of State programs[3] responsible for the regulation of animal feed. Through implementing the AFRPS, a State program is able to achieve and maintain programmatic improvements that help ensure the safety and integrity of the U.S. animal feed supply. Implementation of the AFRPS is voluntary. A State's implementation of the AFRPS helps ensure a uniform and consistent approach to feed regulation among jurisdictions including the sharing of information and the coordination of resources.

The AFRPS is composed of eleven standards that serve as an objective framework to evaluate and improve components of a State feed program. The standards cover the State feed program's regulatory foundation, training, inspection program, auditing, feed-related illness or death and emergency response, enforcement program, outreach activities, budget and planning, laboratory services, sampling program, and assessment and improvement of standard implementation.

Each standard contains a purpose statement, requirement summary, description of program elements, projected outcomes, and a list of required documentation. The program elements describe the best practices of a quality regulatory program. The term "should" is used throughout the AFRPS. Program elements and corresponding conditions described as "should" are best practices but are optional and not required to fully implement a standard. To fully implement the AFRPS, the State program must implement all eleven standards.

Each standard has a self-assessment worksheet except Standard 9: Assessment and Improvement. The State program uses the self-assessment worksheets to determine if the standard's requirements are, or remain, fully met, partially met, or not met. The self-assessments are used to develop an improvement plan for fully implementing the requirements of the standards.

The standards have forms, worksheets, and templates that will help the State program assess and meet the program elements in the standard. State programs are not obligated to use the forms provided in the AFRPS. Other manual or automated forms, worksheets, and templates may be used as long as the pertinent data elements are present. Records and other documents specified in the standards must be maintained in good order by the State program and must be available to verify the information for the purposes of a verification audit. These program standards are not intended to address the performance appraisal processes that a State agency may use to evaluate individual employee performance.

[3] The term "program," as used in this document, means an operational unit(s) that is responsible for the regulatory oversight of feed facilities.

STANDARD 1
Regulatory Foundation

1.1 Purpose

This standard describes the elements of the regulatory foundation[4] used by a State program to regulate animal feed[5].

1.2 Requirement Summary

The State program evaluates the scope of its legal authority and regulatory provisions to perform inspections and investigations, gather evidence, collect samples, and take regulatory actions under State law to ensure the safety and security of feed.

The State program evaluation includes a determination of how the State's legal authority and regulatory provisions correspond to the sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and Federal regulations specified in appendix 1.

1.3 Program Elements

The State program conducts an evaluation to determine whether the State's legal authority and regulatory provisions are equivalent, equivalent in effect, or not equivalent to the sections of the FD&C Act and Federal regulations specified in appendix 1. When conducting such an evaluation, it is advisable that the State program involve qualified legal personnel as appropriate.

- "Equivalent" means that the State law directly references the relevant FD&C Act provision or Federal regulation. The State program specifies the Federal statute or regulation that is incorporated into the State law, including the revision date of the State statutory provision or regulation, the date the Federal statutory provision or regulation was incorporated into the State law, and whether that statutory or regulatory provision is included in whole, in part, or modified from the original. In conducting such an evaluation, the State program should consult with its legal counsel when (1) State law does not provide for incorporation of subsequent revisions of the FD&C Act and CFR, (2) the revision date of the CFR is unknown, or (3) the Federal law or regulation is partially written into State law or regulation.

- "Equivalent in effect" means that the State law has the same regulatory effect as the relevant FD&C Act provision or Federal regulation. A State law may have the same regulatory effect as the Federal law or regulation if either a single State law or rule has

[4] The term "regulatory foundation" as used herein means the laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of an animal feed facility.

[5] "Food" is defined in section 201(f) of the Federal Food, Drug and Cosmetic Act (FD&C Act) in part as articles used for food for animals and articles used for components of such articles. In addition, section 201(w) of the FD&C Act defines "animal feed" as "an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal." The AAFCO Official Publication (OP), 2011 utilizes essentially the same definition of the term "animal feed." For purposes of this document, the term "animal feed" (henceforward referred to as "feed") is used to represent the definitions in FD&C Act sections 201(f), 201(w) and the AAFCO OP, and is inclusive of feed for food-producing animals and pets.

the same regulatory effect as the Federal law or regulation, or when multiple laws of that State are combined and deemed equivalent in effect to a single Federal law or regulation.

- "Not equivalent" means there is no State law equivalent to the relevant Federal law or regulation, there is such a State law but it does not apply to the State's animal feed program, or the Federal and State laws address the same matter but are inconsistent and do not have the same regulatory effect.

In addition, if the State has laws and regulations pertinent to the regulation of animal feed for which there are no comparable Federal provisions, these laws can be listed in appendix 1.

The State program has a documented process, which includes timeframes and procedures, to review the statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that: (1) apply to the regulation of animal feed, (2) delegate authority to the State agency, and (3) describe the State agency's administrative procedures for establishing its authority and incorporating rules by reference.

1.4 Outcome

The State program has conducted an evaluation of the scope of their legal authority and has a regulatory foundation adequate to protect the public health by ensuring the safety and security of feed.

1.5 Documentation

The State program maintains the records listed here.

- Appendix 1: Self-Assessment Worksheet
- Documented process for reviewing appropriate statutes, regulations, rules, ordinances, and other prevailing regulatory requirements
- The statutes, regulations, rules, ordinances, and other prevailing regulatory requirements that: (1) apply to the regulation of animal feed, (2) delegate authority to the State agency, and (3) describe the State agency's administrative procedures for establishing its authority and incorporating rules by reference

STANDARD 2
Training

2.1 Purpose

This standard describes the elements of training for inspectors in a State animal feed regulatory program to ensure they will have the knowledge, skills, and abilities to competently inspect feed facilities and conduct investigations.

2.2 Requirement Summary

The State program establishes and documents a training plan that ensures all inspectors complete course curriculums and field training to adequately perform their work. The plan provides for basic and advanced inspection training as well as continuing education and professional development.

2.3 Program Elements

The State program establishes and documents a basic and advanced animal feed inspection training curriculum that consists of coursework, field training, and continuing education.

The State program provides, or otherwise makes available, inspection training and continuing education for all inspectors.

The State program maintains records documenting the training completed by all inspectors. Appendix 2.2 or a comparable form must be used to document the training that has been completed by an inspector.

For inspectors with greater than five years of experience at the date of the initial self assessment, the State program provides documentation to support completion of basic and advanced curriculums. For subject areas where such documentation is not available, the State program conducts an evaluation of the inspector's previous performance and experience to determine if the inspector has completed the required training or whether additional training is needed.

A. Basic Feed Inspector Training

The State program requires an inspector to successfully complete courses and field training within 24 months from the start date.

The State program establishes and documents basic feed inspection training in the following subject areas.

<u>Subject Areas</u>

- Animal and Public Health Principles: Fundamental animal and public health protection principles that support the foundational roles of the feed inspector

STANDARD 2
Training

- Basic Animal Nutrition: Identify basic means of digestion and nutritional requirements for various animal classes and ingredients that can cause toxicity

- Basic Feed Ingredients, Processing, and Technology: Identify typical ingredients, feedstuffs, processing methods, and technologies commonly used to manufacture animal feed

- Basic National Incident Management System and Incident Command System (ICS): Introduction to the history, principals, and organizational structure of the ICS via ICS100, ICS200, IS700, and IS800

- BSE Awareness: Identify the hazards surrounding ruminant animal by-products being used for animal feed

- Communication: Techniques and skills for effective oral and written communication and interviewing

- Feed Defense: Feed defense principles for the protection of feed from intentional hazard contamination

- Inspections, Compliance, and Enforcement: Conduct entry-level inspections applying the relevant laws and regulations to gather and document evidence to support possible regulatory actions

- Labeling: Basic feed label reviews addressing ingredients, misbranding, and adulteration

- Prevailing Statutes, Regulations, and Policies: Federal and State laws, regulations, and policies appropriate for the entry-level inspector

- Professionalism: Introduction to character conduct, strengths, and values directed toward providing high quality service to the regulated industry and the State program

- Safety: Apply appropriate personal safety and bio-security requirements when conducting field activities

- Sampling: Techniques and skills for collecting various types of samples using the appropriate methods for preparation, collection, and shipping

Coursework may be obtained from sources listed here.

- In-house training provided by a government agency

- Distance learning, for example, satellite downlinks, or web-based training[6]

- Colleges, schools, associations, and research centers

Field training

The State program has an established basic field training program to complement the basic coursework curriculum. The basic field training program is developed by the State and specifies the following:

- Field training checklist of competencies to be mastered and verified in the field and

- Number of joint training inspections required by an inspector.

Joint field training inspections, when an inspector is accompanied by a qualified person designated by the State program, are conducted in firms that represent the feed facilities in the State program inventory as well as the type of routine or basic work that will be performed by the inspector. The inspector must complete the field training program prior to performing independent inspections.

Appendix 2.3 or a comparable form must be used to list the competencies and record the required number of joint field training inspections.

B. Advanced Feed Inspector Training

The State program requires an inspector to successfully complete courses and field training within 60 months from the start date.

The State program establishes and documents advanced feed inspection training in the following subject areas.

Subject Areas

- Advanced Feed Ingredients, Processing, and Technology: Identify ingredients, feedstuffs, processing methods, and technologies that are complex or less common and explore the major elements of modern feed manufacturing and advances in feed technology

- Advanced Labeling: Apply medicated feed and pet food labeling requirements during an inspection

[6] FDA/ORA University classroom and long distance learning courses are listed at: http://www.fda.gov/ora/training/course_ora.html.

STANDARD 2
Training

- Advanced Statutes, Regulations, and Policies: Federal and State laws, regulations, and policies in animal feed and drugs to include bioterrorism regulations

- Animal Sickness and Death Investigation: Assist in outbreak investigations

- Epidemiology: Acquire basic knowledge of epidemiology principles and concepts and apply them to animal outbreak investigations

- Microbiological Pathogens: Distinguish various microbial hazards in feed that could lead to animal or human illness or death

- Traceback and Traceforward Investigations: Determine when a traceback and traceforward are necessary with an implicated product and steps for conducting and concluding the investigation and reporting the results

The State program requires each inspector who is serving in a specialized capacity to conduct the following inspections or assist in emergency responses to complete relevant specialized coursework in the subject areas described here.

- Advanced National Incident Management System and Incident Command Systems (ICS): Required for individuals serving an active role in the ICS. Courses should be specific to the individual's responsibilities but include at a minimum ICS300 and ICS400

- BSE and Ruminant Feeding Ban: Conduct and record inspections of rendering facilities and feed manufactures under the ruminant feed ban regulations, 21 CFR 589.2000 and 21 CFR 589.2001, that prohibit certain cattle materials from being included in any animal feed

- Good Manufacturing Practices Regulations: Conduct inspections and differentiate between the regulations that apply to FDA-licensed medicated feed mills and unlicensed medicated feed mills and the requirements under 21 CFR part 225 Current Good Manufacturing Practice for Medicated Feeds, and 21 CFR part 226 Current Good Manufacturing Practice for Type A Medicated Articles

Coursework may be obtained from sources listed here.

- In-house training provided by a government agency

- Distance learning, for example, satellite downlinks, or web-based training[7]

- Colleges, schools, associations, and research centers

Field training

The State program has an established field training program to complement the advanced coursework curriculum. The advanced field training program is developed by the State and specifies the following:

- Field training checklist of competencies to be mastered and verified in the field and

- Number of joint training inspections required by an inspector.

Joint field training inspections, when an inspector is accompanied by a qualified person designated by the State program, are conducted in firms that are representative of the feed facilities in the State program inventory, as well as the type of advanced work that will be performed by the inspector. The inspector must complete the field training program prior to performing independent inspections requiring advanced skills.

Appendix 2.3 or a comparable form must be used to list the competencies and record the required number of joint field training inspections.

C. Continuing Education

The State program requires that each inspector participate in continuing education. At thirty six month intervals, each inspector is required to receive 36 contact hours[8] of continuing education. The 36-month continuing education interval starts when the advanced training cycle is complete.

The inspector may accrue one contact hour for each clock hour of participation in any of the sources listed here.

- In-house training provided by a government agency

- Distance learning, for example, satellite downlinks or web-based training

- Feed-related courses provided by colleges, schools, associations, and research centers

[7] FDA/ORA University classroom and long distance learning courses are listed at: http://www.fda.gov/ora/training/course_ora.html.

[8] One contact hour equals 60 minutes.

STANDARD 2
Training

The inspector may accrue a maximum of ten contact hours from a combination of the sources listed here.

- Attendance at professional seminars, symposiums, or technical conferences and workshops
- Delivery of presentations at professional conferences
- Providing classroom or field training to new hires
- Publishing an original article in a peer-reviewed professional or trade association journal, periodical, or publication

The inspector may accrue a maximum of four contact hours from reading technical publications related to feed.

2.4 Outcome

The State program has trained inspectors with the knowledge, skills, and abilities to competently inspect feed facilities and conduct investigations.

2.5 Documentation

The State program maintains the records listed here.

- Appendix 2.1: Self-Assessment Worksheet
- Inspector training record
- Competencies for basic and advanced field training
- Documents verifying successful completion of courses for all inspectors

STANDARD 3
Inspection Program

3.1 Purpose

This standard describes the elements of an effective animal feed inspection program.

3.2 Requirement Summary

The State administers an inspection program to determine compliance with animal feed laws.

3.3 Program Elements

A. Risk-Based Inspection Program

The State program defines and maintains an up-to-date inventory of feed facilities[9] whose activities fall under the State's jurisdiction and authority. Inspections are prioritized, frequencies assigned, and resources allocated based on risk factors assigned to a facility or product, the manufacturing processes, and the inspection history of the facility.

The State program is required to use three factors as the basis for categorizing risk. The three required factors are: (1) types of feed and feed products, (2) types of processing, and (3) compliance history of the facility. The State program should also consider optional risk factors, such as volume of feed and feed products manufactured, scope of distribution, and other factors unique to the State's industries and practices. Appendix 3.2 provides additional information about required and optional risk factors and risk categories.

B. Inspection Protocol

The State program has documented policies and procedures for inspecting feed facilities that require the inspectors to

1. Review the feed facility's previous inspection report(s) and complaint(s)
2. Present appropriate credentials and written Notice of Inspection to the feed facility's owner, operator, or agent in charge; make appropriate introductions; explain the purpose and scope of the inspection; and determine inspection authority
3. Follow the safety protocols required by the feed facility and the State program
4. Follow the biosecurity protocols required by the feed facility and the State program
5. Use appropriate equipment and forms needed to conduct inspections
6. Establish interstate jurisdiction for FDA inspections, if applicable

[9] For the purpose of this standard, "feed facility" means a manufacturer, guarantor, or distributor.

7. Recognize the relative risk (high to low) of feed facilities based on the State program's risk-based inspection program and categorization assigned to a facility or product, the manufacturing processes, and the inspection history of the facility
8. Conduct inspection activities, appropriate for the level of risk, focused on those firms, products, and processes determined to be high risk
9. Assess employee activities critical to the safe manufacture, distribution, storage, handling, and disposition of feed
10. Properly evaluate the likelihood that conditions, practices, processes, components, or labeling could cause the product to become adulterated or misbranded
11. Recognize significant non-compliant conditions or practices and document findings consistent with program procedures
12. Distinguish between significant and insignificant observations and isolated incidents versus trends
13. Review and evaluate the appropriate feed facility records and procedures and verify that the procedures are being followed
14. Collect adequate evidence and documentation to support inspection observations in accordance with program procedures
15. Verify correction of deficiencies identified during the previous inspection(s)
16. Conduct activities in a professional manner
17. Use effective interviewing techniques
18. Explain findings clearly and adequately throughout the inspection
19. Alert the feed facility's owner, operator, or agent in charge when an immediate corrective action is necessary
20. Document findings accurately, clearly, legibly, and concisely on the applicable form(s) and provide a copy to the feed facility's owner, operator, or agent in charge
21. Answer questions and provide information as appropriate, and
22. Submit inspection report, sample(s), and supporting documents to headquarters or supervisor in a timely manner

C. Feed Recall Effectiveness Audits

The State program has a system for conducting feed recall effectiveness audits. The system includes documented procedures for receiving, tracking, evaluating, closing, and maintaining records of feed recall effectiveness audits.

D. Consumer Complaints

The State program has a system for handling consumer complaints. The system includes documented procedures for receiving, tracking, evaluating, answering, closing, and maintaining records of consumer complaints.

E. Complaints Resulting from State Program Inspection Activities

The State program has a system to handle complaints from industry about State program inspections. The system includes documented procedures for receiving, evaluating, and maintaining records of industry complaints about State program inspections.

3.4 Outcome

The State program has an animal feed inspection program that may prevent the occurrence of feed adulteration or misbranding by

- focusing inspection resources on high risk facilities, products, processes, and facilities with a poor compliance history
- obtaining immediate corrective actions and long-term compliance improvement from facilities that receive, store, manufacture, process, package, transport, or distribute feed, feed ingredients, pet food, or specialty pet food[10]
- preventing distribution of feed, feed ingredients, pet food, or specialty pet food that may be adulterated or misbranded and to monitor the recall from distribution and disposition of adulterated or misbranded feed

3.5 Documentation

The State program maintains the records listed here.

- Appendix 3.1: Self-Assessment Worksheet
- Documented procedures for defining and updating the State's inventory of feed facilities
- An inventory of feed facilities
- Documented procedures used for categorizing feed facilities based on risk, including the inspection frequency assigned to each defined risk-based category
- Documented policies and procedures for inspecting feed facilities
- Documented procedures for feed recalls, consumer complaints, and industry complaints about State program inspections

[10] AAFCO defines a "specialty pet" as "any domesticated animal normally maintained in a cage or tank, such as, but not limited to, gerbils, hamsters, canaries, psittacine birds, mynahs, finches, tropical fish, goldfish, snakes and turtles, and "specialty pet food" is defined by AAFCO as "any commercial feed prepared and distributed for consumption by specialty pets (AAFCO Official Publication 2011, p. 103). For purposes of this document, the definitions for "specialty pet" and "specialty pet food" have the same meaning as defined by AAFCO.

STANDARD 4
Auditing

4.1 Purpose

This standard describes the auditing procedures necessary to: (1) evaluate the effectiveness of inspections and sample collections, (2) recognize trends in the inspection and sampling programs, and (3) identify areas in need of corrective actions.

4.2 Requirement Summary

The State program conducts audits to document and evaluate the effectiveness of the program's inspections and sample collections. The State program audits field inspections, field inspection reports, sample collections, and sample collection reports.

Audit data is obtained from observing an inspection or sample collection and reviewing the reports.

An audit will be completed on a specified frequency and is based on established performance factors.

4.3 Program Elements

Auditing has two components: (1) a field audit component, which is an on-site performance evaluation of inspection and sample collection and (2) a desk audit component, which is a performance review of the inspection and sample collection reports.

Four types of audits must be conducted by the State program: field inspection audit, field inspection report audit, sample collection audit, and a sample collection report audit. Each type of audit is composed of multiple performance factors that are evaluated and used to calculate an individual's audit score. An individual's audit score determines the audit rating.

Using all of the individual audits, the State program calculates a performance factor score for each performance factor and a cumulative score for each type of audit.

Managers use audit scores, performance factor scores, and cumulative scores to recognize trends in the field inspection and sample collection programs and identify specific areas that need improvement. When any of these scores fall below 80 percent, a corrective action plan is required.

The State program reviews individual audit ratings on a timely and continuous basis.

A review of the performance factor scores and cumulative scores is completed at least every 12 months.

STANDARD 4
Auditing

A. Field Inspection Audit

A qualified auditor conducts field inspection audits to verify that inspections are consistently performed according to established performance factors.

Frequency	A minimum of two field inspection audits of each inspector will be conducted every 36 months. The inspections selected for audits must reflect the inspector's assignments and responsibilities.
Performance Factors	Performance factors are based, at minimum, upon the inspection protocol described in Standard 3: Inspection Program and listed in appendix 4.2.1. For each performance factor, examples of actions and observations that would likely result in a "needs improvement" rating are provided in appendix 4.2.2.
Performance Documentation	Appendix 4.2.1 or comparable form must be used to record the rating of each performance factor, audit score, and audit rating for each field inspection audit. Appendix 4.3, or comparable worksheet, must be used to calculate performance factor scores and a cumulative score. Directions for calculating performance factor scores and the cumulative score can be found in appendix 4.4.

B. Field Inspection Report Audit

Finalized field inspection reports are audited to verify the content quality and that the report was processed according to established performance factors.

Frequency	The State program audits at least 5 percent of all field inspection reports every 12 months. This 5 percent must include all reports from field inspections that were audited. If the reports from field inspections that were audited do not total 5 percent of all reports, the remaining reports should be selected across inspectors, supervisors, inspection types, and geographical locations.
Performance Factors	At a minimum, the performance factors listed in appendix 4.5 must be used.

Performance Documentation	Appendix 4.5, or comparable form, must be used to record the rating of each performance factor, audit score, and audit rating for each inspection report audit. Appendix 4.6, or comparable worksheet, must be used to calculate performance factor scores and a cumulative score. Directions for calculating performance factor scores and the cumulative score can be found in appendix 4.4.

C. Sample Collection Audit

A qualified auditor conducts sample collection audits to verify that sample collections are consistently performed according to established performance factors.

Frequency	A minimum of two sample collection audits of each inspector will be conducted every 36 months. The sample collections selected for audits must reflect the inspector's assignments and responsibilities.
Performance Factors	Performance factors are based, at minimum, upon the inspection protocol described in Standard 11: Sampling Program and listed in appendix 4.7.1. For each performance factor, examples of actions and observations that would likely result in a "needs improvement" rating are provided in appendix 4.7.2.
Performance Documentation	Appendix 4.7.1, or comparable form, must be used to record the rating of each performance factor, audit score, and audit rating for each sample collection audit. Appendix 4.8, or comparable worksheet, must be used to calculate performance factor scores and a cumulative score. Directions for calculating performance factor scores and the cumulative score can be found in appendix 4.4.

D. Sample Collection Report Audit

Finalized sample collection reports are audited to verify the content quality and that the report was processed according to established performance factors.

STANDARD 4
Auditing

Frequency	The State program audits at least 5 percent of all sample collection reports every 12 months. This 5 percent must include all reports from sample collections that were audited. If the reports from sample collections that were audited do not total 5 percent of all reports, the remaining reports should be selected across inspectors, supervisors, sample types, and geographical locations.
Performance Factors	At a minimum, the performance factors listed in appendix 4.9 must be used.
Performance Documentation	Appendix 4.9, or comparable form, must be used to record the rating of each performance factor, audit score, and audit rating for each sample collection report audit. Appendix 4.10, or comparable worksheet, must be used to calculate performance factor scores and a cumulative score. Directions for calculating performance factor scores and the cumulative score can be found in appendix 4.4.

E. Corrective Action Plan

A corrective action plan is required if any of the following occur for any type of audit

- an inspector has an audit score below 80 percent for an individual audit
- a State program has a performance factor score (as a result of all audits over 12 months) below 80 percent for a single performance factor
- a State program has a cumulative score (as a result of all audits over 12 months) below 80 percent

Appendix 4.11, or comparable worksheet, must be used to document performance factors in need of correction, a description of the deficiency, the corrective actions to address the deficiency, and verification that corrective action has been implemented.

4.4 Outcome

The State program's evaluation of its inspection and sample collection activities ensures that they are adequate, complete, and that corrective actions are implemented when necessary.

STANDARD 4
Auditing

4.5 Documentation

The State program maintains the records listed here.

- Appendix 4.1: Self-Assessment Worksheet
- Audit forms used to record performance factor ratings, calculate an audit score, and assign the audit rating for each individual audit
- Performance factor scores and cumulative scores for each audit type conducted over a twelve month period
- Corrective action plan(s)

STANDARD 5
Feed-Related Illness or Death and Emergency Response

5.1 Purpose

This standard describes the functions to detect, identify, and respond to alleged feed-related illnesses, deaths, and emergencies[11], including coordinating roles and responsibilities with other jurisdictions and communicating with appropriate parties.

5.2 Requirement Summary

The State program establishes systems to

- gather and use information to identify feed-related illnesses, deaths, and emergencies
- determine, initiate, and complete an appropriate response to alleged feed-related illnesses, deaths, and emergencies
- maintain and update an emergency contact list
- rapidly notify and report findings to government agencies, departments, or other appropriate parties
- immediately notify law enforcement agencies when intentional feed contamination or feed-related terrorism is suspected or threatened
- release information and communicate with the public

5.3 Program Elements

The State program gathers information to identify incidents of feed-related illnesses, deaths, and emergencies. The State program has procedures to communicate with the appropriate State agencies or departments that investigate animal illnesses and food-related illness and outbreak. These procedures facilitate sharing of information to identify potential feed-related illnesses, deaths, emergencies, and cross-sector events[12].

The State program has a standard operating procedure to evaluate incoming information. Based upon the evaluation, the State program has documented criteria determining the appropriate response as well as the time period in which the appropriate response is to be initiated and completed. For feed-related emergencies, the State program either manages the event using a

[11] "For purposes of this document, an "emergency" is any abnormal situation which, to limit damage to persons, property, or the environment, requires prompt action beyond normal procedures (AAFCO Official Publication 2011, p. 294).
[12] For purposes of this standard, a "cross-sector event" is a feed-related event that impacts human food or an event involving human food that impacts feed.

formalized Incident Command System structure or an official action plan[13] outlining containment, communication, control, and correction protocols.

The State program maintains a list of relevant agencies and emergency contacts and establishes procedures to rapidly notify government agencies, departments, or appropriate parties of relevant findings. Appendix 5.2 provides a template for an emergency contact list. The list is updated frequently. The State program will determine how often updates will occur.

The State program has a process to immediately notify law enforcement agencies when intentional feed contamination or feed-related terrorism is suspected or threatened.

The State program has procedures for releasing information to the public as well as guidelines for coordinating media information with other jurisdictions. The State program provides guidance to consumers and industry to reduce the impact of feed-related illnesses, deaths, or emergencies.

5.4 Outcome

The State program detects, identifies, and responds to feed-related illnesses, deaths, and emergencies within the program's authority. The State program has established communication pathways with government agencies, departments, or appropriate parties to gather and share information to reduce feed-related illnesses, deaths, or emergencies.

5.5 Documentation

The State program maintains the records listed here.

- Appendix 5.1: Self-Assessment Worksheet
- Emergency contact list
- Documented procedures

[13] An example of an official action plan can be found in the AAFCO Emergency Response Preparedness Guidance Document (AAFCO Official Publication 2011 pp.296-297).

STANDARD 6
Enforcement Program

6.1 Purpose

This standard describes the elements of an effective enforcement program.

6.2 Requirement Summary

The State program has documented enforcement strategies. An annual evaluation of the enforcement strategies is conducted to identify potential improvements or modifications.

6.3 Program Elements

The State program has an enforcement program that contains documented enforcement strategies. Enforcement strategies are plans of action designed to prioritize and achieve enforcement goals and are developed by the State program based on critical and chronic violations and violators and contain guidelines for selecting enforcement tools. Appendix 6.2 provides examples of common enforcement tools.

The State program must use the six factors listed in appendix 6.3 when selecting an appropriate enforcement tool. The six factors are

1. Compliance history
2. Responsiveness
3. Scope
4. Nature of the Violation
5. Impact of the Violation
6. Resources

The State program may consider factors in addition to the ones listed above.

The State program will provide a description and relative conditions for all factors. Relative conditions of each factor will be assigned a numerical weight. Appendix 6.3 is an example of factor descriptions, relative conditions, and the associated numerical weights.

The State program has a documented enforcement matrix that is designed to incorporate the relative conditions of each factor and the application of enforcement tools. Appendix 6.4 is an example enforcement matrix.

STANDARD 6
Enforcement Program

The State program conducts an annual evaluation of its enforcement strategies to identify potential improvements or modifications. The State program has a documented process for conducting this evaluation.

6.4 Outcome

The State program has an effective enforcement program with documented enforcement strategies that identify a means to appropriately select and apply enforcement tools. An annual evaluation of the enforcement program is conducted to identify potential improvements or modifications.

6.5 Documentation

The State program maintains the records listed here.

- Appendix 6.1: Self-Assessment Worksheet
- Documented factors including the description, relative conditions, and associated numerical weight for each
- Enforcement matrix
- Documented enforcement strategies
- Documented process for annual evaluation

STANDARD 7
Outreach Activities

7.1 Purpose

This standard describes the elements of outreach activities developed and provided by the State program.

7.2 Requirement Summary

The State program conducts or participates in outreach activities to inform feed industry stakeholders, academia, or consumers about feed topics.

The State program has a plan for outreach activities.

For those outreach activities that are in the form of an event, referred to as an outreach activity event, the State program documents and evaluates such events.

7.3 Program Elements

The State program identifies the methods that will be used for communication with feed industry stakeholders, academia, or consumers.

The State program develops an outreach plan that supports the State program mission and includes the types of activities, target populations, and objectives. The content and design of the plan will vary depending on the State program priorities and mission.

The templates provided in appendix 7.2, or comparable form, is used to record the types of activities (including outreach activity events), target populations, and objectives of an outreach plan.

The State program documents and evaluates outreach activity events. Appendix 7.3, or comparable form, is used to document and evaluate outreach activity events.

7.4 Outcome

The State program uses outreach activities to inform feed industry stakeholders, academia, or consumers about feed topics.

7.5 Documentation

The State program maintains the records listed here.

- Appendix 7.1: Self-Assessment Worksheet
- Outreach plan

STANDARD 7
Outreach Activities

- Outreach activity event overview and evaluation
- Documents to verify the outreach activity event occurred

STANDARD 8
Planning and Resources

8.1 Purpose

This standard describes the elements of workplanning and resource evaluation used by a State animal feed regulatory program.

8.2 Requirement Summary

A State program is required to have a documented workplan to support its inspection and sample collection programs.

A State program is required to conduct an evaluation of resource needs for completing the inspection and sample collection projections identified by the workplan and additional work conducted by the program.

A State program is required to conduct an evaluation of the resources needed to fully implement the Animal Feed Regulatory Program Standards (AFRPS).

8.3 Program Elements

A. Workplan

The State program has a documented workplan. The workplan must include:

- Inspection projections and plan (number, type of inspection, risk category of facility or product, frequency, and completion time),
- Sample projections and plan (number and type of sample), and
- Timeframe that the workplan is applicable.

The State program has a documented procedure for evaluating the workplan. The procedure will detail how the State program conducts periodic and annual evaluations of the workplan and its alignment with program objectives and resources.

FDA and the State program may meet periodically and develop a coordinated workplan.

B. Resources for Inspections, Sample Collections, and Other Program Work

The State program conducts a review of its resources to accomplish the workplan and meet its inspection and sample projections for the applicable workplan timeframe. The resource review should include staffing, equipment, and funding needed to support the inspection and sample collection activities.

STANDARD 8
Planning and Resources

The State program should have adequate staff to inspect the animal feed facilities in its establishment inventory based on the risk categorization and inspection frequency established by the program in its workplan. The State program must develop and use a formula to calculate the number of inspectors needed to conduct inspections. The numerical values in the formula must be verified with data tracked by the State program. The formulas in appendix 8.2 are provided as examples for calculating the number of inspectors needed to conduct inspections. The formulas in appendix 8.2 only include staff numbers needed to conduct inspections and do not include methods for estimating staff numbers needed for sample collections, compliance activities, administrative, or other programmatic activities.
The State program should have adequate staff to conduct sample collections identified in the workplan.

The inspection and sample collection staff must have the equipment needed to conduct inspections and sample collections. A list of the equipment required for inspections and sample collections must be established and maintained by the State program. Appendix 8.3 provides an example list of equipment that may be used for inspections and sample collections.

In addition, the resources needed to train and audit field staff, to support laboratory services, compliance, education and outreach, and to respond to feed-related illnesses, deaths, or emergencies should be determined by the State program. The administrative functions needed to support all program areas should be considered when determining program resources.

C. Resources for Implementing the AFRPS

The State program must conduct a review of the resources required to implement the AFRPS. The resource assessment must be done to determine if the program has adequate staff, equipment, and funding to fully implement each of the program elements in the individual standards. Information technology may be considered as part of the State program's resource needs. Funding, staffing, equipment, and other resources needed to fully implement the individual standards should be identified and recorded in appendix 8.4. A baseline resource evaluation must be made concurrently with the baseline evaluation required for AFRPS Standard 9. Subsequent resource evaluations to determine the resources necessary for the State program to partially meet, fully meet, or maintain full implementation of each standard's requirements must be completed within three years of the previous evaluation.

STANDARD 8
Planning and Resources

8.4 Outcome

The State program has a documented workplan to support its inspection and sample collection programs and assesses the resources needed to support an animal feed regulatory program and implement the Animal Feed Regulatory Program Standards.

8.5 Documentation

The State program maintains the records listed here.

- Appendix 8.1: Self-assessment worksheet
- Workplan
- Documented procedure for evaluating the workplan
- Formula used to calculate number of inspectors and verifying data
- List of required equipment for inspection and sample collection
- Appendix 8.4: Resources for Implementation of AFRPS

STANDARD 9
Assessment and Improvement

9.1 Purpose

This standard describes the processes used to evaluate a State program's fulfillment of the requirements in each standard within the Animal Feed Regulatory Program Standards (henceforth referred to as the standards) and develop improvement plans to address requirements that have not been met.

9.2 Requirement Summary

The State program conducts a baseline evaluation utilizing the self assessments completed for each standard. The results of the baseline evaluation are used to create an improvement plan that aids the program in meeting the requirements of each standard.

The State program regularly evaluates its status in meeting the requirements of the standards.

9.3 Program Elements

The State program uses the self-assessment worksheets to complete a baseline evaluation. The baseline evaluation is used to determine if a standard is fully met, partially met, or not met, and identify areas or functions in the State program that need improving in order to fully meet the requirements of each standard.

Following the baseline evaluation, the State program develops an improvement plan for requirements of the standards that are not fully met. The improvement plan includes the following:

- The individual element or documentation requirement for the standard that was not fully met,
- Improvements needed to fully meet the program element or documentation requirement(s) of the standard,
- Lists of individual tasks that will be used to address the improvement, and
- A projected completion date for each task.

Appendix 9.1, or comparable form, must be used to develop an improvement plan for each standard with the exception of Standard 9: Assessment and Improvement. The State program reviews and updates its improvement plan on an annual basis.

The State program completes an evaluation by reviewing and updating the self-assessment worksheets and required documentation for each standard at least every three years. This evaluation is necessary to determine if each standard's requirements are, or remain, fully met,

partially met, or not met. The State program revises the improvement plan based upon this evaluation.

Appendix 9.2, or comparable form, is used to track implementation status of all the standards.

Documentation related to the evaluation and improvement plans should be maintained by the State program.

If FDA provides a State program with financial assistance to implement the AFRPS, FDA will conduct a verification audit of the State program's AFRPS implementation.

9.4 Outcome

The State program works to meet the requirements of all standards and continues to evaluate and improve the program to ensure the required elements for all standards remain met.

9.5 Documentation

The State program maintains the records listed here.

- Appendix 9.1: Assessment and Improvement Plan
- Completed self-assessment worksheets for each standard
- Improvement plan

STANDARD 10
Laboratory Services

10.1 Purpose

This standard describes the elements of utilizing regulatory testing laboratory[14] services that support the State animal feed program.

10.2 Requirement Summary

The State program has access to laboratory services that provide analytical data that support regulatory functions.

The State program receives accurate, timely, and reliable data from the regulatory testing laboratory.

10.3 Program Elements

The State program maintains a list of routine and non-routine analytical services provided by regulatory testing laboratories as required by the program.

The State program has a documented formal agreement with the laboratory (ies) that conduct routine analytical services, unless the laboratory is managed within the program.

The State program prepares a sample analysis schedule based on a sampling plan[15] in cooperation with laboratories performing routine services to ensure compatibility with laboratory capabilities and capacities. At a minimum, the sample analysis schedule must include the type(s) of feed to be analyzed, number of samples to be collected, estimated timeframe for collection, and type(s) of analysis to be performed.

Standard procedures and a means to communicate necessary information for sample submission, shipping, preservation, storage, retention, disposal, chain of custody, and report of analysis are established in collaboration with the laboratories performing routine services to protect the integrity and identity of the samples sent to the laboratory for analytical testing.

State program utilizes regulatory testing laboratories that:

- Follow AAFCO Quality Assurance /Quality Control guidelines,
- Meet the managerial and technical requirements of ISO/IEC 17025:2005[16], or
- Are accredited by a recognized accreditation body for the appropriate sampling or analytical testing methodology or methodologies.

[14] For purposes of this standard, a "regulatory testing laboratory" is a laboratory that conducts measurements and analyses on food or feed and associated physical samples, which result in qualitative or quantitative analytical findings that may be used as a basis for regulatory action.
[15] A description of a sampling plan can be found in Animal Feed Regulatory Program Standard 11: Sampling Program.
[16] ISO/IEC 17025:2005(E) Second Edition 2005-05-15 Case postale 56. CH-1211 Geneva 20. www.iso.org.

STANDARD 10
Laboratory Services

10.4 Outcome

The State program utilizes valid and defensible laboratory testing data to ensure their mission in protecting animal and public health and enforcing feed regulations.

10.5 Documentation

The State program maintains the records listed here.

- Appendix 10: Self-Assessment Worksheet
- A list of routine and non-routine analytical services and participating routine regulatory testing laboratories
- An agreement with regulatory testing laboratories that provide routine analytical services unless the laboratory is managed within the program
- A current sample analysis schedule based on a sampling plan
- Standard procedures and means to communicate necessary information for sample submission, shipping, preservation, storage, retention, disposal, chain of custody, and report of analysis

STANDARD 11
Sampling Program

11.1 Purpose

This standard describes the elements of an effective animal feed sampling program.

11.2 Requirement Summary

The State program has a sampling program to support an animal feed regulatory program.

11.3 Program Elements

The State program has a documented sampling plan and procedures for collecting surveillance, compliance, investigational, or regulatory samples[17].

A. Sampling Plan

The State program develops, documents, and coordinates an annual sampling plan. This plan is jointly developed and amended by the State program and laboratories performing routine services within a timeframe sufficient to allow for advanced planning and scheduling of work. The sampling plan outlines the State program's sampling priorities, the sample analysis schedule, and availability or coordination of analytical support. The sampling plan may include estimates of analytical costs.

B. Sampling Procedures

The sampling procedures must include: (1) methods for collecting, storing, and transporting samples and (2) instructions for documenting the sample collection.

1. Methods for Collecting, Storing, and Transporting Samples

    a. Follow safety precautions on feed labels

    b. Follow the State program's safety protocol for collecting samples

    c. Use appropriate method and equipment to collect the sample

    d. Seal sample to initiate chain of custody

    e. Maintain and document sample integrity, security, and chain of custody

    f. Issue receipt[18] for sample

[17] Regulatory samples may be used to support inspection observations.
[18] Receipt could include cost of sample and method of payment.

g. Handle[19], package, and ship sample using procedures appropriate to prevent compromising condition of sample

h. Deliver or ship sample to the appropriate laboratory within acceptable timeframes

2. Instructions for Documenting the Sample Collection

a. Date of the sample collection

b. Product identification including name, manufacturing codes, date codes, lot numbers, batch codes, expiration dates, and any other referencing manufacture identification

c. Description of product

d. Method of collection, lot sampled, lot size, and any special techniques used to collect sample

e. Location where sample was collected

f. Name and address of responsible party, guarantor, possessor, or distributor

g. Sample type (surveillance, compliance, investigational, or regulatory)

h. Analysis requested, if applicable

i. Product labels, including customer-formula feed labels, are collected or reproduced

j. Receiving and distribution information

11.4 Outcome

The State program has a sampling program that aligns sampling resources with State program priorities. The sampling plan will facilitate efficient use and coordination of resources to obtain timely information. Samples are collected, stored, transported, and documented to support regulatory actions.

[19] Includes storing sample.

STANDARD 11
Sampling Program

11.5 Documentation

The State program maintains the records listed here.

- Appendix 11: Self-Assessment Worksheet
- Documented sampling plan
- Documented sampling procedures

Appendix 1: Self-Assessment Worksheet

Instructions: Determine if State laws and regulations are "Equivalent," "Equivalent in Effect," or "Not Equivalent" to Federal statutes and regulations. If there is no State law or regulation that is Equivalent or Equivalent in Effect, mark the Not Equivalent box; otherwise list the State law or regulation citation and complete the columns for either Equivalent or Equivalent in Effect as appropriate. The Notes section can be used to detail differences between State and Federal laws and regulations.

		Not Equivalent	State Citation	Equivalent			Equivalent in Effect	Notes
				Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial/ Full	Legal Review Date	
Federal Food, Drug & Cosmetic Act								
201	Definitions (f), (g), (k), (m), (s), (v) and (w)							
301	Prohibited acts (a), (b), (c), (d), (e), (f), and (k)							
303*	Penalties							
304**	Seizure							
401	Definitions and standards for food							
402	Adulterated food (a)-(c)							
403	Misbranded food (a)-(n)							
404	Emergency permit control							
406	Tolerances for poisonous ingredients in food							
408	Tolerances and exemptions for pesticide chemical residues							
409	Food additives							

*Penalties may vary from Federal statute.
**Although the State program may not have authority for seizure, the State program could have legal authority to stop adulterated and misbranded products from moving in commerce, for example, detention, stop-sale orders, withdrawal from distribution, and embargoes.

Appendix 1: Self-Assessment Worksheet (continued)

		Not Equivalent	State Citation	Equivalent			Equivalent in Effect	Notes
				Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial/ Full	Legal Review Date	
501	Adulterated drugs and devices (ONLY: 501(a)(2)(B) and 501(a)(6))							
504	Veterinary feed directive drugs							
512	New animal drugs (ONLY: 512(a)(2))							
701	Regulations and hearings							
704	Factory inspection							
Title 21 Code of Federal Regulations: Food and Drugs (2011)								
1	General enforcement regulations (ONLY §§ 1.20-1.23)							
7	Enforcement policy (ONLY §§ 7.1-7.13 and §§ 7.40-7.59)							
70	Color additives (ONLY §§ 70.20-70.25)							
73	Listing of colors exempt from certification (ONLY §§ 73.1-73.615)							
74	Listing of color additives subject to certification (ONLY §§ 74.101-74.706)							
81	General specifications and general restrictions for provisional color additives for use in foods, drugs, and cosmetics							

Appendix 1: Self-Assessment Worksheet (continued)

		Not Equivalent	State Citation	Equivalent			Equivalent in Effect	Notes
				Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial/ Full	Legal Review Date	
82	Listing of certified provisionally listed colors and specifications (ONLY §§ 82.3-82.706)							
225	Current good manufacturing practice for medicated feeds							
226	Current good manufacturing practice for Type A medicated articles							
500.23	Thermally processed low-acid foods packaged in hermitically sealed containers (refers to regulations in 21 CFR 113)							
500.24	Emergency permit control (refers to regulations in 21 CFR 108 - ONLY §§ 108.25- 108.35)							
500.29	Gentian violet for use in animal feed							
500.45	Use of polychlorinated biphenyls (PCB's) in the production, handling, and storage of animal feed							
500.50	Propylene glycol in or on cat food							
500.80 - 500.92	Regulation of carcinogenic compounds used in food-producing animals							
501	Animal food labeling							

Appendix 1: Self-Assessment Worksheet (continued)

		Not Equivalent	State Citation	Equivalent			Equivalent in Effect	Notes
				Revision Date of Federal Law/Regulation	Date Incorporated into State Law	Partial/ Full	Legal Review Date	
502	Common or usual name for nonstandardized animal foods							
509	Unavoidable contaminants in animal food and food-packaging material							
510	New animal drugs (ONLY Subpart D - Records and Reports)							
558	New animal drugs for use in animal feeds							
570	Food additives (EXCEPT § 570.6, § 570.15, and §570.17)							
573	Food additives permitted in feed and drinking water of animals							
579	Irradiation in the production, processing, and handling of animal feed and pet food							
582	Substances generally recognized as safe							
584	Food substances affirmed as generally recognized as safe in feed and drinking water of animals							
589	Substances prohibited from use in animal food or feed							

Additional State Authorities (optional):
Instructions: List any State Authorities used by the State program that are pertinent to the regulation of animal feed but do not have a comparable Federal statute or regulation (examples: tolerance for mycotoxins, fluorine, or noxious weeds in feed).

Additional notes and comments:

Assessment Completed By:

Name

Date

Appendix 2.1: Self-Assessment Worksheet

Inspector Training Record Summary

Instructions: This chart is used to document and track inspectors' training status. Enter the name of all active inspectors. Include the start date of employment, and record the date the inspector completed the coursework and field training for the basic and advanced curriculums. For continuing education, indicate the number of contact hours completed. For training record column, indicate if there is a training record (appendix 2.2) for the inspector as well as all documents verifying completion of courses.

Employee Name	Start Date	Basic Curriculum		Advanced Curriculum		Contact Hours	Training Record
		Course	Field	Course	Field		

Field Training Program

Instructions: Indicate with a Y (Yes) or N (No) if the following components have been developed and documented for both the basic and advanced field training programs.

Component	Basic Field	Advanced Field
Checklist of Competencies		
Number of Joint Inspections		

Assessment Completed By:

Name _____ Date _____

Appendix 2.2: Inspector Training Record

Inspector Name: _____ **Employment Start Date:** _____

A. Basic Feed Inspector Training

Instructions: If the inspector has greater than five years of experience and an evaluation of the inspector's previous performance and experience shows adequate training has been completed, mark the Name and Location of Training Column, with "Met via Evaluation."

Subject Areas	Name and Location of Training	Completion Date	Inspector Initials	Supervisor Initials	Documentation Verifying Completion (Y/N)
Animal and Public Health Principles					
Basic Animal Nutrition					
Basic Feed Ingredients, Processing, and Technology					
Basic National Incident Management System and Incident Command System					
BSE Awareness					
Communication					
Feed Defense					
Inspections, Compliance, and Enforcement					
Labeling					
Prevailing Statutes, Regulations, and Policies					
Professionalism					
Safety					
Sampling					

Appendix 2.2: Inspector Training Record (continued)

Inspector Name: _____

Instructions: Record the name of the firm where the joint training inspection took place as well as the competencies covered.

Basic Field Training (Name and Location of Firm)	Competencies Covered	Completion Date	Inspectors Initials	Supervisor Initials	Mastered (Y/N)

Appendix 2.2: Inspector Training Record (continued)

Inspector Name: _____

B. Advanced Feed Inspector Training

Instructions: If the inspector has greater than five years of experience and an evaluation of the inspector's previous performance and experience has found that no additional training for a subject area is needed, mark the Name and Location of Training Column, with "Met via Evaluation."

Subject Areas	Name and Location of Training	Completion Date	Inspector Initials	Supervisor Initials	Documentation Verifying Completion (Y/N)
Advanced Feed Ingredients, Processing, and Technology					
Advanced Labeling					
Advanced Statutes, Regulations, and Policies					
Animal Sickness and Death Investigation					
Epidemiology					
Microbiological Pathogens					
Traceback and Traceforward Investigations					
Specialized Advanced					
Advanced National Incident Management System and Incident Command Systems					
BSE and Ruminant Feeding Ban					
Good Manufacturing Practices Regulations					

Appendix 2.2: Inspector Training Record (continued)

Inspector Name: _____

Instructions: Record the name of the firm where the joint training inspection took place as well as the competencies covered

Advanced Field Training (Name and Location of Firm)	Competencies Covered	Completion Date	Inspectors Initials	Supervisor Initials	Mastered (Y/N)

Appendix 2.2: Inspector Training Record (continued)

Inspector Name: _____

C. Continuing Education

Type of Activity	Name and Location of Activity	Completion Date	Inspectors Initials	Supervisor Initials	Contact Hours Earned

Appendix 2.3: Field Training Competencies

A. Basic Field Competencies

Instructions: List the competencies to be covered in the State program's basic field training and provide a short description.

Competency	Description

Minimum Number of Joint Field Training Inspections Required: _____

Appendix 2.3: Field Training Competencies (continued)

B. Advanced Field Competencies

Instructions: List the competencies to be covered in the State program's advanced field training and provide a short description.

Competency	Description

Minimum Number of Joint Field Training Inspections Required: _____

Appendix 3.1: Self-Assessment Worksheet

Program Elements	Yes/No	Specific Reference [20]	Notes
Section I. Risk-Based Inspection Program			
a. Has the State program defined a feed facility inventory? • Is the State program defined feed facility inventory updated? • Is there contact information for firms listed in the inventory?			
b. Does the State program define risk categories for feed facilities according to risk-based factors of the facility or product, manufacturing process, and inspection history of the facility?			
c. Does the State program assign risk categorization to feed facilities according to risk-based factors of the facility or product, manufacturing process, and inspection history of the facility?			
d. Are risk categories used to prioritize inspections, assign inspection frequencies, and allocate resources?			
Section II. Inspection Protocol			
Does the program's inspection protocol require inspectors to:			
a. Review the feed facility's previous inspection report(s) and complaints?			
b. Present appropriate credentials and written Notice of Inspection to the feed facility's owner, operator, or agent in charge; Make appropriate introductions; explain the purpose and scope of the inspection; and determine inspection authority?			
c. Follow the safety protocols required by the feed facility and the State program?			
d. Follow the biosecurity protocols required by the feed facility and the State program?			
e. Use appropriate equipment and forms needed to conduct inspections?			
f. Establish interstate jurisdiction for FDA inspections, if applicable?			
g. Recognize the relative risk (high to low) of feed facilities based on the State program's risk-based inspection program and categorization assigned to a facility or product, the manufacturing processes, and the inspection history of the facility?			

[20] Cite the reference (title and date of publication, section, and page number) to demonstrate the program element has been met.

Program Elements	Yes/No	Specific Reference	Notes
h. Conduct inspection activities focused on those firms, products, and processes determined to be high risk?			
i. Assess employee activities critical to the safe manufacture, distribution, storage, handling, and disposition of feed?			
j. Properly evaluate the likelihood that conditions, practices, processes, components, or labeling could cause the product to become adulterated or misbranded?			
k. Recognize significant non-compliant conditions or practices and document findings consistent with program procedures?			
l. Distinguish between significant and insignificant observations and isolated incidents versus trends?			
m. Review and evaluate the appropriate feed facility records and procedures and verify that the procedures are being followed?			
n. Collect adequate evidence and documentation to support inspection observations in accordance with program procedures?			
o. Verify correction of deficiencies identified during the previous inspection(s)?			
p. Conduct activities in a professional manner?			
q. Use effective interviewing techniques?			
r. Explain findings clearly and adequately throughout the inspection?			
s. Alert the feed facility's owner, operator, or agent in charge when an immediate corrective action is necessary?			
t. Document findings accurately, clearly, legibly, and concisely on the applicable form(s) and provide a copy to the firm's owner, operator, or agent in charge?			
u. Answer questions and provide information as appropriate?			
v. Submit inspection report, sample(s), and supporting documents to headquarters or supervisor in a timely manner?			
Section III. Feed Recall Effectiveness Audits			

a. Does the recall system include documented procedures for receiving, tracking, evaluating, closing, and maintaining records of feed recall effectiveness audits?			
Program Elements	**Yes/No**	**Specific Reference**	**Notes**
Section IV. Consumer Complaints			
a. Does the consumer complaint system include documented procedures for receiving, tracking, evaluating, answering, closing, and maintaining records of consumer complaints?			
Section V. Complaints Resulting from State Program Inspection Activities			
a. Does the industry complaint response system include documented procedures for receiving, evaluating, and maintaining records of industry complaints about State program inspections?			

Assessment Completed By:

Name

Date

Appendix 3.2: Risk Categorization for Feed Facilities

Determining Risk Factors for Feed Facilities
Standard 3 requires a State program to categorize feed facilities based on risk and to allocate resources and establish inspection frequencies based upon that categorization. State programs should document their categorization and inspection frequencies. Differences between State programs will exist for many reasons including variable resources, legislative mandates, localized industries and practices, and competing priorities.

A key requirement of this standard is that the State program uses a risk-based method for categorizing feed facilities with a baseline inspection frequency specified for each category.

State programs must categorize feed facilities based on at least the following three factors: (1) the type of processing, (2) type of feed, and (3) compliance history of the feed facility.

The State program should consider optional risk factors such as volume of product manufactured, scope of distribution, or other factors unique to the State's industries and practices.

The risk associated with each factor may be scored with numerical values that are tabulated to rank the feed facilities and prioritize inspections.

Risk Categorization Factors for Feed Facilities

A. Required Factors

1. Type of Processing
The following types of processing should be considered.

- Rendering
- Pelleting
- Extrusion
- Roasting
- Steam Flaking
- Refrigeration
- Mixing
- Milling
- Salvaging
- Thermal processing
- Heating

2. Type of Feed
The following types of feed should be considered.

- Mixed species
- Raw pet food
- Pet food
- Medicated feed
- Customer formula feed
- Feed containing prohibited mammalian tissue
- Feed ingredients subject to adulterants such as mycotoxins, pesticides, or industrial chemicals
- Single specie feed
- Non-medicated feed

3. Compliance History

The following types of compliance history should be considered.

- Poor history
- No history
- Inconsistent history
- Good history

The following is an example of a risk associated with a required factor.

Risk	Score	Compliance History
High	3	Feed facility with poor history of compliance or no compliance history with feed laws and regulations
Medium	2	Feed facility with an inconsistent history of compliance
Low	1	Feed facility is routinely in compliance with feed laws and regulations

B. Optional Factors

1. Volume of Product Manufactured

- Greater than 500 tons/day
- 50 to 500 tons/day
- Less than 50 tons/day

2. Scope of Distribution

- Global
- National
- Interstate
- Regional
- Intrastate
- County
- Local

Appendix 4.1: Self-Assessment Worksheet

Field Inspection Audit

Yes	No	
		Program conducts field inspection audits
		12-month period of performance:
		Number of audits conducted:
		Number of corrective action plans required:
		Inspectors are audited at a minimum against the performance factors found in appendix 4.2.1
		Audits reflect inspector's assignments and responsibilities
		Two audits per inspector completed every 36 months
		Audit score calculated for each individual audit
		Audit rating recorded for each individual audit
		Performance factor score calculated for each performance factor
		Cumulative score calculated for the program

Field Inspection Report Audit

Yes	No	
		Program conducts inspection report audits
		12- month period of performance:
		Number of inspection reports completed:
		Number of inspection reports audited:
		Number of corrective action plans required:
		A minimum of 5 percent of inspection reports were audited
		Inspection reports are audited at a minimum against the performance factors found in appendix 4.5
		Audit score calculated for each individual audit
		Audit rating recorded for each individual audit
		Performance factor score calculated for each performance factor
		Cumulative score calculated for the program

Sample Collection Audit

Yes	No	
		Program conducts sample collection audits
		12-month period of performance:
		Number of audits conducted:
		Number of corrective action plans required:
		Inspectors are audited at a minimum against the performance factors found in appendix 4.7.1
		Audits reflect inspector's assignments and responsibilities
		Two audits per inspector completed every 36 months
		Audit score calculated for each individual audit
		Audit rating recorded for each individual audit
		Performance factor score calculated for each performance factor
		Cumulative score calculated for the program

Appendix 4.1: Self-Assessment Worksheet (continued)

Sample Collection Report Audit

Yes	No	
		Program conducts sample collection report audits
		12-month period of performance:
		Number of sample collections reports reviewed:
		Number of sample collection reports audited:
		Number of corrective action plans required:
		A minimum of 5 percent of sample collection reports were audited
		Sample collection reports are audited at a minimum against performance factors found in appendix 4.9
		Audit score calculated for each individual audit
		Audit rating recorded for each individual audit
		Performance factor score calculated for each performance factor
		Cumulative score calculated for the program

Corrective Action Plan

Yes	No	
		Program develops corrective action plans when
		An inspector has an audit score below 80 percent for an individual audit
		The program has a performance factor score below 80 percent for a single performance factor
		The program has a cumulative score below 80 percent

The corrective active plan includes:

Yes	No	
		Performance factor(s) in need of correction
		Description of the deficiency
		Corrective actions to address the deficiency
		Date of next audit

Assessment Completed By:

Name _____ Date _____

Appendix 4.2.1: Field Inspection Audit Form

Field Inspection Audit	
Inspector:	Auditor: Date of Audit:
Firm Name: Firm Address:	Type of Inspection: ☐ BSE ☐ GMP ☐ Tissue Residue ☐ Complaint ☐ Other:
Total Number of: Acceptable Needs Improvement Audit Score:	Audit Rating: ☐ Acceptable ☐ Needs Improvement

Instructions to the Auditor:
All performance factors must be rated 'Acceptable' or 'Needs Improvement.' The total number of 'Acceptable' and 'Needs Improvement,' as well as the audit score and audit rating, must be recorded in the space above.

To calculate the audit score: *Audit Score = [# Acceptable/ (# Acceptable + # Needs Improvement)] x 100*.

If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement.'

I. Pre-Inspection Assessment

1. Did the inspector review the feed facility's previous inspection report(s) and complaints?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Did the inspector use appropriate equipment and forms to conduct the inspection?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

II. Inspection Observations and Performance

1. Did the inspector present appropriate credentials and written Notice of Inspection to the owner, operator, or agent in charge? Make appropriate introductions, explain the purpose and scope of the inspection, and determine inspection authority?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Did the inspector follow safety protocols required by the feed facility and the state program?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

Appendix 4.2.1: Field Inspection Audit Form (continued)

3. Did the inspector follow the bio-security protocols required by the feed facility and the state program? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
4. Did the inspector establish interstate jurisdiction for FDA inspections, if applicable? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
5. Did the inspector recognize relative risk (high to low) of the feed facility based on the state program's risk-based inspection program and categorization assigned to a facility or a product, the manufacturing processes, and the inspection history of the facility? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
6. Did the inspector conduct inspection activities focused on the feed facility's products and processes determined to be high risk? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
7. Did the inspector assess feed facility employee activities critical to the safe manufacture, distribution, storage, handling, and disposition of feed? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
8. Did the inspector properly evaluate the likelihood that conditions, practices, processes, components, or labeling could cause the product to become adulterated or misbranded? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
9. Did the inspector recognize significant non-compliant conditions or practices and document findings consistent with program procedures? ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)

10. Did the inspector distinguish between significant and insignificant observations and isolated incidents versus trends?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

11. Did the inspector review and evaluate the appropriate feed facility records and procedures and verify that the procedures are being followed?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

12. Did the inspector collect adequate evidence and documentation to support inspection observations in accordance with program procedures?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

13. Did the inspector verify correction of deficiencies identified during the previous inspection(s)?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

14. Did the inspector conduct activities in a professional manner?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

III. Oral and Written Communications

1. Did the inspector use effective interviewing techniques?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

2. Did the inspector explain findings clearly and adequately throughout the inspection?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

3. Did the inspector alert the feed facility's owner, operator, or agent in charge when an immediate corrective action was necessary?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

4. Did the inspector document findings accurately, clearly, legibly, and concisely on the applicable form(s) and provide a copy to the feed facility's owner, operator, or agent in charge?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

5. Did the inspector answer questions and provide information as appropriate?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

IV. General Comments

Enter any general comments or recommendations as a result of this audit.

Name of Auditor	Signature of Auditor	Date

Appendix 4.2.2: Completing the Field Inspection Audit Form

For each performance factor, examples of actions and observations that would likely result in a "needs improvement" rating are provided.

Pre-Inspection Assessment

1. **Did the inspector review the previous feed facility's inspection report(s) and complaints?**

   Examples of a "needs improvement" rating

   a. The inspector does not review the previous inspection report and complaints.

   b. The inspector does not review a firm's response letter to the previous establishment inspection in which corrective actions were promised.

2. **Did the inspector use appropriate equipment and forms to conduct the inspection?**

   Examples of a "needs improvement" rating

   a. The inspector does not have a copy or have electronic access to the pertinent laws and regulations.

   b. During a medicated feed mill inspection, the inspector does not have a current copy of Title 21 of the *Code of Federal Regulations* Parts 225 and 558 (or a current Feed Additive Compendium) or access on line.

   c. The inspector does not have a calculator.

   d. The inspector does not have a camera to document violations.

   e. The inspector does not have a flashlight to examine poorly lit raw material storage areas.

   f. The inspector uses outdated, improper, or inappropriate forms for the type of inspection conducted.

Inspection Observations and Performance

1. **Did the inspector present appropriate credentials and written Notice of Inspection to the feed facility's owner, operator, or agent in charge? Make appropriate introductions, explain the purpose and scope of the inspection, and determine inspection authority?**

   Example of a "needs improvement" rating

   a. Inspector fails to present credentials to the owner, operator, or agent in charge of the establishment.

   b. Inspector fails to make appropriate introductions, explain the purpose and scope of the inspection, and determine inspection authority.

   c. Inspector enters the firm through the rear entrance and immediately begins the inspection without issuing a notice of inspection.

   d. Upon entering the firm, the inspector fails to issue the notice of inspection to the appropriate person.

   e. Inspector uses only a business card as identification.

2. **Did the inspector follow safety protocols required by the feed facility and the State program?**

   Example of a "needs improvement" rating

   a. The inspector does not ask if any particular safety protocols are mandated at the facility.

   b. The inspector does not follow the State program's safety protocol or use personal protective equipment appropriately.

   c. The inspector does not follow the safety protocols mandated by a particular facility.

3. Did the inspector follow the bio-security protocols required by the feed facility and the State program?

Example of a "needs improvement" rating

a. The inspector does not inquire if any particular bio-security protocols are mandated at the facility.

b. The inspector does not follow the State program's bio-security protocol.

c. The inspector does not follow the bio-security protocols mandated by the feed facility.

4. Did the inspector establish interstate jurisdiction for FDA inspections, if applicable?

Examples of a "needs improvement" rating

a. The inspector fails to confirm the interstate movement of product or ingredients.

b. The inspector conducts an inspection of a licensed feed mill. The inspector fails to determine that product or ingredients have been received or shipped in interstate commerce by the manufacturer since the last inspection.

5. Did the inspector recognize relative risk (high to low) of the feed facility based on the State program's risk-based inspection program and categorization assigned to a facility or a product, the manufacturing processes, and the inspection history of the facility?

Examples of a "needs improvement" rating

a. The inspector does not recognize the relative risk of the facility because the inspector is not knowledgeable with the manufacturing process involved at this facility and does not inquire with facility personnel.

b. The inspector organizes inspection activities focused on low risk items and ignores high risk products and processes.

6. Did the inspector conduct inspection activities focused on the feed facility's products and processes determined to be high risk?

Examples of a "needs improvement" rating

a. The inspector does not prioritize high risk inspection activities.

b. The inspector concentrates inspection activities on low risk items and not high risk products and processes.

7. Did the inspector assess feed facility employee activities critical to the safe manufacture, distribution, storage, handling, and disposition of feed?

Examples of a "needs improvement" rating

a. The inspector conducts the inspection without input from employees responsible for critical activities.

b. The inspector does not review employee training records when required.

c. The inspector observes a trash bin and a reclaim bin in the same area, but he fails to evaluate practices sufficiently to identify an employee placing trash in the reclaim bin, which subsequently re-enters the process flow.

d. The inspector fails to recognize distressed dog food being placed into a re-grinder bin containing regrinds for ruminant feed.

e. The inspector fails to note an employee using medication in a feed when the formula does not call for the addition of this medication.

8. Did the inspector properly evaluate the likelihood that conditions, practices, processes, components, or labeling could cause the product to be adulterated or misbranded?

Examples of a "needs improvement" rating

a. The inspector does not observe critical activities during the inspection and does not discuss procedures in place to prevent distribution when an error has occurred.

b. The inspector does not review labeling protocols and verify a system was in place to assure proper labeling.

c. The inspector does not recognize possible adulterants (pesticides) that are stored above bagged feeds.

d. The inspector does not investigate a pallet of stacked bags that lack labeling and identification.

e. The inspector fails to investigate feed containing an unapproved drug combination.

9. Did the inspector recognize significant non-compliant conditions or practices and document findings consistent with program procedures?

Examples of a "needs improvement" rating

a. The inspector concentrates on one item and does not recognize other significant non-compliant conditions.

b. The inspector notices non-compliant products but fails to adequately address them at the time of the inspection or at the end of the inspection.

c. Inspector fails to identify a feed containing an unapproved drug combination.

d. The inspector fails to note the significance of "back hauling" prohibited materials in a bulk truck used to transport cattle feed.

10. Did the inspector distinguish between significant and insignificant observations and isolated incidents versus trends?

Examples of a "needs improvement" rating

a. The inspector keeps reviewing documents until he finds an insignificant violation.

b. The inspector does not emphasize the severity or outcome of significant observations and the need for immediate action.

c. The inspector does not discuss patterns or trends that were observed.

d. The inspector does not recognize significant pest infestations.

e. The inspector identifies and objects to record keeping deficiencies without considering that corrective action plans have been implemented by the firm and the deficiency has not reoccurred.

11. Did the inspector review and evaluate the appropriate feed facility records and procedures and verify the procedures are being followed?

Examples of a "needs improvement" rating

a. The inspector asks for the invoices for customer formula feeds for labeling information and does not realize that the facility's procedures use the facility's mix ticket as the label.

b. The inspector notices drugs are being added to the mixer before any other ingredient when the facility's SOP for addition of medications states that medications will be added at five minutes into the mix time.

c. The inspector fails to question alarm notifications and the resulting required procedures.

d. The inspector encounters out of limit drug assays and does not look for follow up actions.

e. The inspector reviews mixer cleanout records but fails to note cleanouts were not done according to the facility's SOP.

12. Did the inspector collect adequate evidence and documentation to support inspection observations in accordance with program procedures?

Examples of a "needs improvement" rating

a. The inspector reviews the drug inventory and notes that the drug inventory is not accurate but does not collect documents to support the finding.

b. The inspector notices dead rodents around the mixer hand add area and does not provide supporting evidence such as photographs, detailed narrative, or affidavits.

c. The inspector mentions that proper caution statements are missing from medicated feed labels yet does not provide copies of the labeling involved.

d. The inspector simply notes that "housekeeping needs improved" and does not provide documentation to support the observation.

13. Did the inspector verify correction of deficiencies identified during the previous inspection(s)?

Examples of a "needs improvement" rating

a. The previous inspection of the facility listed inaccurate drug levels on labeling of several feeds. During the current inspection, the manager informs the inspector that the problem has been corrected. The inspector simply notes in the report the management's statement and does not verify that the labels have been changed.

b. The previous inspection noted improper cleanout procedures for all handling equipment. The inspector verifies that the mixer is being adequately cleaned out but does not verify proper procedures are being used for other handling equipment.

c. The previous inspection noted that production records were not being checked at the end of the day. The inspector notes there are initials on some of the records, but the inspector does not further inquire about their procedures.

14. Did the inspector conduct activities in a professional manner?

Examples of a "needs improvement" rating

a. The inspector does not dress appropriately for the inspection. Upon arrival, clothes were torn and dirty.

b. The inspector fails to wear protective safety equipment that is required by the firm or the State.

c. The firm asks the inspector to use the boot bath before entering the production area, but the inspector ignores the firm's request and enters the production area.

d. The inspector is rude and demanding

Oral and Written Communications

1. Did the inspector use effective interviewing techniques?

Examples of a "needs improvement" rating

a. The inspector's requests for information are ambiguous; consequently, the firm provides documents that are not relevant to the inspection.

b. The inspector's requests contain jargon unfamiliar to the firm causing confusion in the facility personnel responses to inspector.

c. The inspector is confrontational.

d. The inspector asks pointed and directed questions in order to solicit a desired response.

e. The inspector is not a good listener and kept interrupting the facility personnel in their responses.

2. Did the inspector explain findings clearly and adequately throughout the inspection?

Examples of a "needs improvement" rating

a. The inspector does not discuss a significant deficiency observed in the shelled corn storage or conveyor system before proceeding to the hammer mill area although the general manager was present at the time.

b. At the conclusion of the inspection, the inspector's discussion of the deficiencies is vague; therefore, management is unclear of the significance of the observations and that corrective action should be taken by the firm.

c. At the conclusion of the inspection, the inspector does not discuss a significant deficiency observed during the inspection.

3. Did the inspector alert the feed facility's owner, operator, or agent in charge when an immediate corrective action was necessary?

Examples of a "needs improvement" rating

a. The inspector fails to advise the firm manager that ruminant feed products containing prohibited material are being packaged and shipped.

b. The inspector fails to notify the firm manager that he witnessed direct contamination of bagged feed ingredients with used motor oil.

c. After witnessing direct product contamination with a toxic chemical, the inspector immediately notifies an employee who was not the most responsible person in the feed facility.

4. Did the inspector document findings accurately, clearly, legibly, and concisely on the applicable form(s) and provide a copy to the feed facility's owner, operator, or agent in charge?

Examples of a "needs improvement" rating

a. The inspector fails to list significant inspectional observations.

b. An inspectional observation states, "Firm did not control hazards," but no further explanation is provided.

c. The report is illegible or contains several spelling and grammatical errors.

d. Inspector does not leave a summary of inspectional observations with the firm's owner, operator, or agent in charge.

5. Did the inspector answer questions and provide information as appropriate?

Examples of a "needs improvement" rating

a. The inspector reveals specific information about a pending compliance action against a competitor.

b. The inspector provides a competitor's formulation to the facility manager.

c. The inspector falsely answers a policy question that leads the firm to take an inappropriate corrective action.

Appendix 4.3: Field Inspection Audit Worksheet

State Program: _____ **Reviewed By:** _____

Performance Period: _____ **Date:** _____

Cumulative Score (5): _____

Auditor Initials and Date of Audit (1)																			A_t (3)	NI_t (3)	Performance Factor Score (3)
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
II.1																					
II.2																					
II.3																					
II.4																					
II.5																					
II.6																					
II.7																					
II.8																					
II.9																					
II.10																					
II.11																					
II.12																					
II.13																					
II.14																					
III.1																					
III.2																					
III.3																					
III.4																					
III.5																					
Audit Score (2)																					
																			Subtotal - ***Enter the sum of the totals from all continuation sheets.***		
																			Total (4) - ***Enter the final sums (subtotal + sums of (3) on this form).***		

(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.

Appendix 4.3: Field Inspection Audit Worksheet (continuation sheet)

State Program: _____ **Reviewed By:** _____

Auditor Initials and Date of Audit (1)																			A_t (3)	NI_t (3)	Performance Factor Score (3)
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
II.1																					
II.2																					
II.3																					
II.4																					
II.5																					
II.6																					
II.7																					
II.8																					
II.9																					
II.10																					
II.11																					
II.12																					
II.13																					
II.14																					
III.1																					
III.2																					
III.3																					
III.4																					
III.5																					
Audit Score (2)																					
																			Subtotal - ***Enter the sum of the totals from all continuation sheets.***			
																			Total (4) - ***Enter the final sums (subtotal + sums of (3) on this form).***		

(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.

Appendix 4.4: Instructions for Completing Audit Worksheets

The four audit worksheets allow the State program to recognize trends and identify specific areas in the inspection and sample collection programs that may need improvement.

Worksheets found in appendices 4.3, 4.6, 4.8, and 4.10 are used to calculate performance factor scores and a cumulative score for a twelve month performance period. A performance factor score or cumulative score below eighty percent indicates the need for improvement and requires corrective action.

Instructions: The numbers listed in parentheses on each of the worksheets correspond to the numbered instructions below (e.g. Auditor Initials and Date of Audit (1) on the worksheet is number 1. below).

1. For each audit, record the auditor's initials and date of audit.

2. For each audit, record the rating for each performance factor (A = Acceptable; NI = Needs Improvement) as well as the audit score.

3. Count the number of A and NI for each performance factor (row), and record the total number of acceptable and needs improvements ratings, as well as calculate the performance factor score.

   A_t = Total Number of Acceptable Ratings
   NI_t = Total Number of Needs Improvement Ratings

   Performance Factor Score = $[A_t / (A_t + NI_t)] \times 100$

4. Sum the Total Number of Acceptable and Total Number of Needs Improvement ratings for all audits.

   $\sum A_t$ = Sum of Total Number of Acceptable Ratings
   $\sum NI_t$ = Sum of Total Number of Needs Improvement Ratings

   Note: $\sum$ is the statistical symbol for the sum of all numbers

5. Calculate the cumulative score for all audits. Record the cumulative score in the space provided in the box located at the top of Worksheet.

   Cumulative Score = $[\sum A_t / (\sum A_t + \sum NI_t)] \times 100$

6. Identify and make notes about trends and single performance factors rated as Needs Improvement in multiple audits.

Appendix 4.5: Field Inspection Report Audit Form

Field Inspection Report Audit	
Auditor:	Date of Audit: Date of Inspection:
Firm Name: Firm Address:	Type of Inspection: ☐ BSE ☐ GMP ☐ Tissue Residue ☐ Complaint ☐ Other:
Total Number of: Acceptable Needs Improvement Audit Score:	Audit Rating: ☐ Acceptable ☐ Needs Improvement

Instructions to the Auditor:
All performance factors must be rated 'Acceptable' or 'Needs Improvement.' The total number of 'Acceptable' and 'Needs Improvement,' as well as the audit score and audit rating, must be recorded in the space above.

To calculate the audit score: *Audit Score = [# Acceptable/(# Acceptable + # Needs Improvement)] x 100.*

If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement.'

I. Organization of the Report

1. Format of the inspection report followed the State program's current policies and procedures.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Required fields on inspection report or related report forms are completed.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

3. Written observations were clear and concise.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

4. Submitted report within timeframes.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

Appendix 4.5: Field Inspection Report Audit Form (continued)

II.	Record of Findings
1.	Recorded name and title of facility managers and key personnel. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
2.	Recorded name and title of personnel interviewed during the inspection. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
3.	Recorded findings not in compliance with laws and regulations. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
4.	Recorded significant findings (if any). ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
5.	Recorded the collection of all samples, exhibits, photographs, or photocopies to support findings. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
6.	Recorded any refusals encountered during the inspection. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
III.	**Communication with Facility Personnel**
1.	Provided a summary of findings. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)
2.	Recorded responses, replies, or corrective action commitments. ☐ Acceptable ☐ Needs Improvement Comments (required for Needs Improvement)

Appendix 4.5: Field Inspection Report Audit Form (continued)

IV.	General Comments
Enter any general comments or recommendations as a result of this audit.	

Name of Auditor	Signature of Auditor	Date

Appendix 4.6: Field Inspection Report Audit Worksheet

State Program: _____ **Reviewed By:** _____

Performance Period: _____ **Date:** _____

Cumulative Score (5): _____

Auditor Initials and Date of Audit (1)																			**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
II.1																					
II.2																					
II.3																					
II.4																					
II.5																					
II.6																					
III.1																					
III.2																					
Audit Score (2)																					
Subtotal - *Enter the sum of the totals from all continuation sheets.*																					
Total (4) - *Enter the final sums (subtotal + sums of (3) on this form).*																					

(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.

Appendix 4.6: Field Inspection Report Audit Worksheet (continuation sheet)

State Program: _____ **Reviewed By:** _____

Auditor Initials and Date of Audit (1)																			A_t (3)	NI_t (3)	Performance Factor Score (3)
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
II.1																					
II.2																					
II.3																					
II.4																					
II.5																					
II.6																					
III.1																					
III.2																					
Audit Score (2)																					
Subtotal - ***Enter the sum of the totals from all continuation sheets.***																					
Total (4) - ***Enter the final sums (subtotal + sums of (3) on this form).***																					

(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.

Appendix 4.7.1: Sample Collection Audit Form

Sample Collection Audit	
Inspector:	Auditor: Date of Audit:
Firm Name: Firm Address:	Type of Sample Collection: ☐ Surveillance ☐ Compliance ☐ Investigational ☐ Regulatory ☐ Other:
Total Number of: Acceptable Needs Improvement Audit Score:	Audit Rating: ☐ Acceptable ☐ Needs Improvement

Instructions to the Auditor:
All performance factors must be rated 'Acceptable' or 'Needs Improvement.' The total number of 'Acceptable' and 'Needs Improvement,' as well as the audit score and audit rating, must be recorded in the space above.

To calculate the audit score: *Audit Score = [# Acceptable/(# Acceptable + # Needs Improvement)] x 100.*

If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement.'

I. Sample Collection Observations and Performance

1. Did the inspector follow safety precautions on the feed label?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Did the inspector follow the State program's safety protocol for collecting samples?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

3. Did the inspector use the appropriate method and equipment to collect the sample?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

4. Did the inspector seal the sample to initiate chain of custody?
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

Appendix 4.7.1: Sample Collection Audit Form (continued)

5. Did the inspector maintain and document sample integrity and security?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

6. Did the inspector issue a receipt for samples?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

7. Were the samples handled, packaged, and shipped using procedures appropriate to prevent compromising the condition of the sample?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

8. Was the sample delivered or shipped to the appropriate laboratory within acceptable timeframes?
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

II. General Comments

Enter any general comments or recommendations as a result of this audit.

Name of Auditor _____ Signature of Auditor _____ Date _____

Appendix 4.7.2: Completing the Sample Collection Audit Form

For each performance factor, examples of actions and observations that would likely result in a "needs improvement" rating are provided.

Sample Collection Observations and Performance

1. **Did the inspector follow safety precautions on the feed label?**

   Examples of a "needs improvement" rating

   a. The inspector does not review all labeling that accompanies the feed prior to sampling.

   b. The inspector does not have a label available prior to sampling.

   c. The inspector does not review the whole container or back of label.

   d. The inspector is not knowledgeable about the nature and use of the product they are sampling.

2. **Did the inspector follow the State program's safety protocol for collecting samples?**

   Examples of a "needs improvement" rating

   a. The inspector does not have a copy or have electronic access to the State program's safety protocol.

   b. Inspector does not have proper personal protective equipment that may be needed.

   c. The inspector takes bulk samples out of a bulk vehicle and does not use appropriate fall protection equipment.

3. **Did the inspector use the appropriate method and equipment to collect the sample?**

   Example of a "needs improvement" rating

   a. Inspector simply hand grabs three or four handfuls out of the top of one bag.

   b. Inspector collects a sample of a Type A medicated article and then collects a complete feed for a different species without cleaning sampling equipment in between samples to prevent cross-contamination.

   c. Inspector pours half of his collected sample into the firm's container because the firm requested they have a portion of his sample.

   d. Inspector collects ten probes from ten fifty pound bags but does not seal the probe holes or left the product in an unsalable condition.

   e. The inspector does not have a copy or have electronic access to the State program's sampling procedures.

   f. The inspector collects ten probes for a lot of feed. Eight of the sample cores are white in color and two are green. The inspector does not note this on the sample collection form or investigate it further.

   g. A sample is to be tested for microbial activity, but the inspector does not follow proper aseptic protocols.

   h. Inspector calls ahead to the facility and requests they have samples collected by the facility's personnel and ready for pickup.

4. **Did the inspector seal the sample to initiate chain of custody?**

   Example of a "needs improvement" rating

   a. The inspector collects three samples in the facility but does not document and seal the open samples until returning to his car.

   b. The inspector seals the container in such a manner whereby it can be opened without breaking the official custody seal.

5. Did the inspector maintain and document sample integrity and security?

Example of a "needs improvement" rating

a. The inspector does not complete the required information (e.g. lot identification number, date of collection, or guarantees) on the sample collection report.

b. The inspector collects a sample of feed and seals the sample with the wrong official custody seal.

c. High fat samples are placed in containers where the fat may leach into the container (e.g. paper bags).

d. The label on a sampled feed says to store in a cool dry place, but during a period of high temperature, the collected sample is left in a car trunk for several days prior to shipment to the laboratory.

6. Did the inspector issue a receipt for samples?

Examples of a "needs improvement" rating

a. The inspector collects a sample and does not issue a receipt describing the sample to the owner, operator, or agent in charge.

b. The inspector tells the owner he would mail him the receipt later in the week.

7. Were the samples handled, packaged, and shipped using procedures appropriate to prevent compromising the condition of the sample?

Examples of a "needs improvement" rating

a. The feed samples are packaged along with other substances (e.g. pesticides or fertilizers) that might contaminate the sample during shipment.

b. The samples are not packaged to prevent breakage, spillage, crushing, or other detrimental actions that may be encountered in shipping the samples.

8. Was the sample delivered or shipped to the appropriate laboratory within acceptable timeframes?

Examples of a "needs improvement" rating

a. The samples are not shipped or delivered according to the State program's protocols.

b. A feed sample containing urea is shipped to the fertilizer laboratory instead of the feed laboratory.

c. A sample of corn, intended to be tested for aflatoxin contamination, is delivered to the State's seed testing laboratory instead of the proper feed laboratory.

Appendix 4.8: Sample Collection Audit Worksheet

State Program: _____ **Reviewed By:** _____

Performance Period: _____ **Date:** _____

Cumulative Score (5): _____

Auditor Initials and Date of Audit (1)																			A_t (3)	NI_t (3)	Performance Factor Score (3)
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
I.5																					
I.6																					
I.7																					
I.8																					
Audit Score (2)																					
Subtotal - ***Enter the sum of the totals from all continuation sheets.***																					
Total (4) - ***Enter the final sums (subtotal + sums of (3) on this form).***																					

(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.

Appendix 4.8: Sample Collection Audit Worksheet (continuation sheet)

State Program: _____ **Reviewed By:** _____

Auditor Initials and Date of Audit (1)																			**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
I.5																					
I.6																					
I.7																					
I.8																					
Audit Score (2)																					
Subtotal - *Enter the sum of the totals from all continuation sheets.*																					
Total (4) - *Enter the final sums (subtotal + sums of (3) on this form).*																					

(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.

Appendix 4.9: Sample Collection Report Audit Form

Sample Collection Report Audit	
Auditor:	Date of Audit: Date of Sample Collection:
Firm Name: Firm Address:	Type of Sample Collection: ☐ Surveillance ☐ Compliance ☐ Investigational ☐ Regulatory ☐ Other:
Number of: Acceptable Needs Improvement Audit Score:	Audit Rating: ☐ Acceptable ☐ Needs Improvement

Instructions to the Auditor:
All performance factors must be rated 'Acceptable' or 'Needs Improvement.' The total number of 'Acceptable' and 'Needs Improvement,' as well as the audit score and audit rating, must be recorded in the space above.

To calculate the audit score: *Audit Score = [# Acceptable/(# Acceptable + # Needs Improvement)] x 100.*

If the audit score is below eighty percent, the audit rating must be marked as 'Needs Improvement.'

I. Organization of the Report

1. Date of sample collection was recorded.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

2. Product identification including name, manufacturing codes, date codes, lot numbers, batch codes, expiration dates, and any other referencing manufacture identification was recorded.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

3. Description of product was recorded.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

4. Collection information including method of collection, lot sampled, lot size, and any special techniques used to collect sample was recorded.
   ☐ Acceptable ☐ Needs Improvement

   Comments (required for Needs Improvement)

5. Location where sample was collected was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

6. Name and address of responsible party, guarantor, possessor, or distributor were recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

7. Sample type (surveillance, compliance, investigational, or regulatory) was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

8. Analysis requested was recorded, if applicable.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

9. Product labels, including customer-formula feed labels, are collected or reproduced.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

10. Receiving and distribution information was recorded.
☐ Acceptable ☐ Needs Improvement

Comments (required for Needs Improvement)

II. General Comments

Enter any general comments or recommendations as a result of this audit.

Name of Auditor | Signature of Auditor | Date

Appendix 4.10: Sample Collection Report Audit Worksheet

State Program: _____ **Reviewed By:** _____

Performance Period: _____ **Date:** _____

Cumulative Score (5): _____

Auditor Initials and Date of Audit (1)																			A_t (3)	NI_t (3)	Performance Factor Score (3)
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
I.5																					
I.6																					
I.7																					
I.8																					
I.9																					
I.10																					
Audit Score (2)																					
Subtotal - ***Enter the sum of the totals from all continuation sheets.***																					
Total (4) - ***Enter the final sums (subtotal + sums of (3) on this form).***																					

(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.

Appendix 4.10: Sample Collection Report Audit Worksheet (continuation sheet)

State Program: _____ **Reviewed By:** _____

Auditor Initials and Date of Audit (1)																			**A_t (3)**	**NI_t (3)**	**Performance Factor Score (3)**
Initials																					
Date																					
Performance Factors (2)	**Performance Ratings**																				
I.1																					
I.2																					
I.3																					
I.4																					
I.5																					
I.6																					
I.7																					
I.8																					
I.9																					
I.10																					
Audit Score (2)																					
Subtotal - ***Enter the sum of the totals from all continuation sheets.***																					
Total (4) - ***Enter the final sums (subtotal + sums of (3) on this form).***																					

(6) Use this space to identify and make notes about trends and single performance factors rated as "Needs Improvement" in multiple audits.

Appendix 4.11: Corrective Action Plan

Type of Audit: ☐ Field Inspection Audit ☐ Sample Collection Audit
☐ Field Inspection Report Audit ☐ Sample Collection Report Audit

Instructions: The corrective action for each deficiency reported during an audit should be described in the table below. The corrective action plan should be maintained with the originating audit documents.

Performance Factor (record number from audit form)	Description of Deficiency	Corrective Action(s)	Verification that Corrective Action Implemented

Completed By:

Name _____ Date _____

Appendix 5.1: Self-Assessment Worksheet

Instructions: Specify if each item has been developed. If yes, specify the document reference.

Gathering Information

State program has	Yes	No	Document Reference
Procedure to communicate with			
Agency/Department(s) investigating animal illness			
Agency/Department(s) investigating animal deaths			
Agency/Department(s) investigating feed emergencies			
Agency/Department(s) investigating food-related illness			

Evaluation and Response

State program has	Yes	No	Document Reference
Standard operating procedure to evaluate incoming information			
Documented criteria that determines appropriate response			
Incident management via (select one)			
Formalized Incident Command System structure			
Official action plan			

Communication

State program has	Yes	No	Document Reference
List of relevant agencies and emergency contacts			
Procedures to			
Notify government agencies and departments			
Notify law enforcement			
Notify appropriate parties			
Release information to public*			
Guidelines for coordinating media information with other Jurisdictions			

*Includes guidance to consumers and industry to reduce impact of feed-related illnesses, deaths, or emergencies

Assessment Completed By:

Name _____ Date _____

Appendix 5.2: Emergency Contact List

This template may be used to develop an emergency contact list. The content, design, and frequency of update should be determined by the State program.

Agency	Contact Name	Phone Number	Email
Intra-Agency			
Supervisor		(w) (c)	
Laboratory		(w) (c)	
Office of General Counsel		(w) (c)	
Office of the Director or Administration		(w) (c)	
Office of Legislative Affairs		(w) (c)	
Office of Public Information		(w) (c)	
Federal Government			
Department of Homeland Security		(w) (c)	
Food and Drug Administration		(w) (c)	
Department of Health and Human Services		(w) (c)	
Center for Disease Control and Prevention		(w) (c)	
Environmental Protection Agency		(w) (c)	
U.S. Department of Agriculture		(w) (c)	
Energy Department		(w) (c)	
Department of Defense		(w) (c)	
National Security Administration		(w) (c)	

Appendix 5.2: Emergency Contact List (continued)

Agency	Contact Name	Phone Number	Email
Federal Bureau of Investigation		(w) (c)	
Trade Commission		(w) (c)	
Health Department		(w) (c)	
Customs Service		(w) (c)	
Justice Department		(w) (c)	
Veterinary Medical Diagnostic Lab		(w) (c)	
State/Provincial/Local Government Offices			
Department of Conservation, Natural Resources, or Environmental Protection Agency		(w) (c)	
Department of Agriculture, Plant Board, or Forestry		(w) (c)	
Board of Pharmacy		(w) (c)	
State Chemist		(w) (c)	
Department of Public Safety		(w) (c)	
Department of Public Health Human Services, Social Services		(w) (c)	
State Veterinarian, Animal Health, Livestock Commission		(w) (c)	
Attorney General		(w) (c)	
Department of Commerce		(w) (c)	

Appendix 5.2: Emergency Contact List (continued)

Agency	Contact Name	Phone Number	Email
Department of Wildlife and Fisheries		(w) (c)	
Department of Marine Resources		(w) (c)	
Department of Professional Regulation/Inspection		(w) (c)	
Veterinary Medical Diagnostic Laboratory		(w) (c)	
Land Grant University/Extension Service		(w) (c)	
Police, Sheriff, Constable		(w) (c)	
Fire Department		(w) (c)	
Hospital (local or regional)		(w) (c)	
Utilities: Gas, Electric, Water, Sewage		(w) (c)	
Industry Organizations			
Producer Associations (ex: cattle feeders, pork producers, poultry producers)		(w) (c)	
National Grain and Feed Associations		(w) (c)	
American Feed Industry Association		(w) (c)	
Pet Food Institute		(w) (c)	
Feed Advisory Committee (Board) Members		(w) (c)	
Equipment Suppliers Association		(w) (c)	

Appendix 5.2: Emergency Contact List (continued)

Agency	Contact Name	Phone Number	Email
Additional Assistance			
Forensics Laboratory		(w) (c)	
Poison Control Center		(w) (c)	
Toxicology		(w) (c)	
Pathology		(w) (c)	
Universities/University "Centers"		(w) (c)	
Federal, State, and Local Emergency Management Agencies		(w) (c)	

Update Completed By:

Name

Date

Appendix 6.1: Self-Assessment Worksheet

Instructions: The State program should identify if they have a specified component then evaluate if it includes the associated components. If the State program has the main component and associated components check 'Yes,' if not, check 'No.' The State program should maintain the documented procedures listed in this appendix.

Yes	No	
		Documented enforcement strategies (plans of action)

Yes	*No*	*Enforcement Strategies*
		Based on critical and chronic violations and violators
		Contain guidelines for selecting enforcement tools

Notes:

Yes	No	
		Utilize the following factors for selecting enforcement tools

- Compliance history
- Responsiveness
- Scope
- Nature of Violation
- Impact of Violation
- Resources

Yes	*No*	
		Each factor has a documented factor description
		Each factor has relative conditions
		Numerical weight is assigned to each relative condition

Notes:

Yes	No	
		Documented enforcement matrix

Notes:

Yes	No	
		Documented process for evaluating enforcement strategies

Notes:

Yes	No	
		Conducted annual evaluation of enforcement strategies

Date Completed: _____

Notes:

Assessment Completed By:

_____ _____

Name Date

Appendix 6.2: Enforcement Tools

This appendix is a list of common enforcement tools that may be used by State feed inspection programs. An explanation of each tool has been provided.

Advisory or informational letter - can be used as a form for both compliance assistance and education and would usually apply to non-repetitive violations of no risk to health, safety, or the environment. Administrative violations involving licensing, product registration, and payment of fees are examples.

Warning letters with or without a required response - usually used to clearly outline the violation and require corrective action(s). The letter might or might not request a written response upon correction. This tool would be appropriate for violations that have or could present risk to health, safety, or the environment. Further, it could be appropriate for repetitive administrative violations.

Withdrawal from distribution orders - used when health, safety, or the environment would be put at risk from distribution of a feed. It might also be used when other tools have failed to achieve compliance for serious administrative violations or gross labeling violations.

Informal hearings or meetings - used to provide an opportunity to bring together parties to discuss and understand the nature of a violation. It may lead to an agreed order or consent decree. Use of this tool would be appropriate for many violations including those that may be chronic; threats to health, safety or the environment; civil penalties, license denials, revocation, or other serious administrative actions. This tool may be used in conjunction with others to facilitate compliance.

Mediation - meeting of all parties that produces a consent decree or compliance agreement.

Civil penalty - monetary penalty assessed for a violation. Civil penalty fines are based on a numeric point matrix determined by the severity of the violation and the repeat nature of the offense. A notice shall be given and an opportunity for an administrative (formal) hearing must be provided. This tool should be used in addition to other tools to prevent chronic violations or to address illegal acts when other tools are not available. Where appropriate, an informational letter, warning letter, informal hearing or meeting, or administrative hearing should precede the use of civil penalties.

Cancellation, probation, or conditional status - actions that can be taken against a license, permit, or registration due to repeat violations, including reporting of distributions, payment of fees, or chronic analytical deficiencies.

Administrative hearing - opportunity for an administrative (formal) hearing is provided to the regulated establishment prior to the issuance of a civil penalty, license denial, or license revocation. An administrative hearing may result in a consent decree with the regulated establishment. This tool should be used in chronic violations or when threats to health or safety exist.

Condemnation and confiscation - may be applied to any lot of non-compliant feed and may involve a court in the local area. A feed found violative by the court may be subject to condemnation and disposition after first allowing the claimant or manufacturer an opportunity to seek release of the feed or request opportunity to reprocess or re-label the feed for compliance. This tool would be appropriate for use when a practice or product presents a risk to health, safety, or the environment. It may also be applicable in other cases such as chronic violations.

Injunction - may be used to restrain a firm from any or all violations. The tool would be used in case of a serious threat of immediate or irreparable harm. Use may also be appropriate to restrain a firm from operation in wanton violation of a chronic nature involving administrative aspects of the law.

Criminal prosecution - may be pursued against a firm or person that impedes, obstructs, hinders, or otherwise prevents or attempts to prevent enforcement of commercial feed regulation. This tool can be used for any violation, but other tools may be appropriate.

Appendix 6.3: Factors, Descriptions, and Numerical Weights for Consideration When Selecting an Enforcement Tool

The following six factors must be used by the State program to develop an enforcement matrix: compliance history, responsiveness, scope, nature of the violation, impact of the violation, and resources.

Below are example descriptions of these six factors, including numerical weights[21] and assigned relative conditions. The descriptors, numerical weights, and relative conditions listed below are examples. The State program may consider these examples when developing the descriptors, numerical weight, and relative conditions that will be utilized by the State program for the six factors that must be included in an enforcement matrix. The State program may consider additional factors.

The sum of the numerical values for all of the factors can be used to help select the appropriate enforcement tool from an enforcement matrix (see appendix 6.4 for an example).

Factor 1 – Compliance History

The compliance history of the firm or individual can be indicative of their commitment to assuring they are operating in compliance. Compliance history can include inspections, sample analysis, label reviews, and previous enforcement actions. It should include consideration of whether corrections were promised and completed, whether corrections were made promptly, and whether the same or similar problems occur repeatedly. The following relative weights can be used in assessing the firm's compliance history.

(0) firm has extensive history and is always found in compliance
(1) no history on file for this firm
(2) firm's history shows only minor violations, always corrected
(3) firm's history shows instances of significant violations or repeated minor violations
(4) firm's history shows instances of significant violations and promised corrections are rarely made

Factor 2 - Responsiveness

The responsiveness of the firm or individual can also be used to help assess their commitment to assuring they are operating in compliance and the level of enforcement action needed to encourage commitment. Does the firm promise correction and follow through? Are they aware of laws, regulations, and requirements for their operation? Do they have quality assurance or training programs? Do they accept responsibility for problems that are uncovered? Are corrections made promptly? Do they make corrections while an inspector is there but do not maintain the correction? When appropriate, do they examine similar systems and/or products to make overall correction? The following relative weights can be used in assessing the responsiveness of the firm.

(0) accept responsibility for assuring compliance; aware of the requirements or have quality assurance or training programs; corrections are promised and made promptly; when appropriate, extend corrections to similar products or systems
(1) accept responsibility for assuring compliance; aware of the requirements; corrections promised but not made in a timely manner or corrections are not sustained
(2) do not accept responsibility for assuring compliance; not aware of the requirements; no promise of correction; no correction

[21] Source of the factors, descriptions, and numerical weights is the AAFCO Enforcement Guidelines-Factor Application section of the AAFCO 2011 Official Publication (pp. 288-290).

Factor 3 - Scope

Scope of the firm's business as well as the scope of the violation can be an important factor in choosing an appropriate enforcement action. Is the distribution of violative products limited to local distribution, multiple counties, Statewide, multiple States, nationwide, or worldwide? What is the quantity of violative product involved? How many animals are affected? Are the violative products intended for a limited or unique population, or are they for a broader population? Does the violation involve a single product or multiple products? Is the violation specific to a single lot? Is the violation a process violation? Is this an industry practice? The following relative weights can be used in assessing the scope of the violation.

(1) very limited distribution, quantity, or limited purchaser; violation is limited to a single lot
(2) distribution is limited to Statewide or bordering States; violation is limited to one or two products; quantity of product distributed is relatively small or the number of animals effected is relatively small; non critical process violation
(3) distribution is unlimited and may involve large quantities of product or affect a large number of animals; violation involves critical processes or multiple products

Factor 4 - Nature of the Violation

The nature of the violation has an impact on the type of enforcement action and may influence whether the action focuses on the product, process, or individual. Consider whether the violations are minor or significant; whether they are sporadic or continuous; whether they involve only record keeping or control issues or they include product defects or contaminations; whether they are the result of human error; whether they were the result of lack of knowledge and understanding of the firm or individual's responsibility or the legal requirements; or whether the violations were done knowingly or deliberately. When determining whether the violation is significant or not as significant, or whether it would be a major or minor violation, available and current science and policy should be considered. The following relative weights can be used in assessing the nature of the violation.

(1) minor labeling violations or minor sporadic record keeping violations
(2) violations are not minor but they are isolated incidents, the result of human error, or the result of lack of knowledge about requirements
(4) significant GMP or labeling violations; contaminations; fraud
(8) deliberate, knowing violations that result in hazard to public health

Factor 5 - Impact of the Violation

Selecting the most appropriate enforcement tool is strongly tied to the impact the violation has on the user of the product (economic impact or fraud), the safety of the animal, and human health safety. The State program should consider whether the violations affect food producing or non-food producing animals. Are the violations economic or fraudulent in nature? Do the violations compromise animal safety? Do the violations pose a risk to human health safety? Is there a particular population at risk such as children, immuno-compromised, or the elderly? The following relative weights can be used in assessing the impact of the violation.

(1) minor economic or fraud violations
(4) animal safety concerns
(8) human health safety concern but limited population
(10) human health safety concern with a risk to all populations

Factor 6 - Resources

Consider what resources the State program has to devote to the violative findings. Has the State program established overall compliance goals and objectives? Are the State program's enforcement efforts prioritized? Are the resources devoted in part to special initiatives? Has the State program established communication networks to determine if the violations have been encountered elsewhere? Are there other agencies that may be able to pursue action consistent with the State program's compliance goals? The following relative weights can be used in assessing the impact of the violation.

(1) no resources are available
(2) limited resources are available
(3) ample resources are available

Appendix 6.4: Enforcement Matrix

Instructions: This is an example that can be used to develop the State program's enforcement matrix. The enforcement matrix should be designed to incorporate the relative conditions of each factor (with a minimum of the six factors listed in Standard 6: Enforcement Program) identified by the State program. The enforcement matrix can be used to aid the State program in determining which enforcement tool to apply. The content, design, and frequency of update should be determined by the State program.

Directions for Use of the Enforcement Matrix:

1. Determine the violation categories. The Example Enforcement Matrix provides five examples of major violation categories: labeling, GMPs, sample results, contaminations, and administrative.

2. For each violation category, identify the enforcement tools that are appropriate for the violation category and the factor value range from minor to major. Examples of enforcement tools for each violation category from minor violations (factor value range 4 to 8) to major violations (factor value range 20 to 29) are provided in the Example Enforcement Matrix.

3. Calculate the sum of the numerical values assigned to each factor. See below for an example calculation:

Factor	Relative Condition Noted	Numerical Value
1. Compliance History	Firm's history shows only minor violations, always corrected (2)	2
2. Responsiveness	Accept responsibility for assurance compliance (0)	0
3. Scope	Distribution is limited to Statewide and/or border states (2)	2
4. Nature of the Violation	Minor labeling violations (1)	1
5. Impact of the Violation	Minor economic or fraud violations (1)	1
6. Resources	Limited resources are available (2)	2
	Sum of Numerical Values for Each Factor =	8

4. Locate the "Factor Value Range" that corresponds with the calculated sum of the numerical value for all factors. The matrix can be modified to different amounts of factor value ranges and values within each factor range. Using the example calculation in item 3, the sum of the numerical values is 8. The available enforcement tools for factor value range from 4 to 8 are "no action" and "information letter." The State could choose between these two enforcement tools for the violations reported.

5. Choose the appropriate enforcement tool for the violation category based on the factor value range.

Example Enforcement Matrix[22]

Violation Category	Factor Value Range			
	4 to 8	**9 to 12**	**13 to 19**	**20 to 29**
Labeling	No Action Information Letter	Warning Letter Stop Sale Informal Hearing/Mediation	Condemnation/Seizure Informal Hearing/Meeting Injunction Refer to Other Agency Civil Penalty	Prosecution Formal Hearing Injunction Refer to Other Agency Civil Penalty
GMPs	No Action Information Letter	Warning Letter Stop Sale Informal Hearing/Mediation	Condemnation/Seizure Informal Hearing/Meeting Injunction Refer to Other Agency Civil Penalty	Prosecution Formal Hearing Injunction Refer to Other Agency Civil Penalty
Sample Results	No Action Information Letter	Warning Letter Stop Sale Informal Hearing/Mediation	Condemnation/Seizure Informal Hearing/Meeting Injunction Refer to Other Agency Civil Penalty	Prosecution Formal Hearing Injunction Refer to Other Agency Civil Penalty
Contaminations	No Action Information Letter	Warning Letter Stop Sale Informal Hearing/Mediation	Condemnation/Seizure Informal Hearing/Meeting Injunction Refer to Other Agency Civil Penalty	Prosecution Formal Hearing Injunction Refer to Other Agency Civil Penalty
Administrative	No Action Information Letter	Warning Letter Stop Sale Informal Hearing/Mediation	Condemnation/Seizure Informal Hearing/Meeting Injunction Refer to Other Agency Civil Penalty	Prosecution Formal Hearing Injunction Refer to Other Agency Civil Penalty

[22] The example enforcement matrix was derived from the Example Violation Chart found in the AAFCO Enforcement Guidelines-Factor Application section of the AAFCO 2011 Official Publication (pp. 288-290).

Appendix 7.1: Self-Assessment Worksheet

Instructions: The State program should identify if they have a specified component then evaluate if it includes the associated components. If the State program has the main component and associated components check 'Yes,' if not, check 'No.'

Yes	No	
		The State program has identified methods used to communicate with feed industry, stakeholders, academia, or consumers

Notes:

Yes	No	
		The State program has an outreach plan

Yes	*No*	*The outreach plan includes:*
		Types of activities
		Target populations
		Objectives

Notes:

Yes	No	
		The State program documents outreach activities

Notes:

Yes	No	
		The State program documents and evaluates outreach activity events

Notes:

Assessment Completed By:

Name _____ Date _____

Appendix 7.2: Outreach Plan

Either of the templates below can be used to develop an outreach plan. The content, design, and frequency of update should be determined by the State program.

A. Outreach Plan in Chart Format

Effective Dates: _____

Type of Outreach Activity	Target Population	Objective	Delivery Method

Completed By:

_____ _____

Name Date

B. Outreach Plan in Paragraph Format

Effective Dates: _____

Outreach Objective 1: _____

List and provide details of outreach activities that will be used to help support this objective, including the audience that will be reached and the method of delivery.

Outreach Objective 2: _____

List and provide details of outreach activities that will be used to help support this objective, including the audience that will be reached and the method of delivery.

Outreach Objective 3: _____

List and provide details of outreach activities that will be used to help support this objective, including the audience that will be reached and the method of delivery.

Completed By:

_____ _____

Name Date

Appendix 7.3: Outreach Activity Event Overview and Evaluation

Instructions: Attach documents such as agendas, meeting summaries, and program evaluations to this form.

Section I. Overview of Outreach Activity Event

A. Type of outreach activity event (select all that apply)

☐ Meeting ☐ Workshop ☐ Task Force/Committee

☐ Extension Event ☐ Other: _____

B. Date of outreach activity event: _____

C. Subject or name of outreach activity event: _____

D. Objective of outreach activity event: _____

E. Target population for outreach activity event: _____

Section II. Evaluation of Outreach Activity Event

Program Elements	Yes/No	If no, please explain
A. The purpose and objectives were clearly defined		
B. The context of the training activity was consistent with the objectives		
C. An evaluation was completed by attendees		
D. State program reviewed and discussed comments from attendees		

Describe what went well, what could be done better, and what more could be done to improve the outreach activity.

Completed By:

Name _____ Date _____

Appendix 8.1: Self-Assessment Worksheet

Instructions: The State program should identify if they have a specified component then evaluate if it includes the associated components. If the State program has the main component and associated components check 'Yes,' if not, check 'No.' The State program should maintain the documented procedures listed in this appendix.

Yes	No	
		Documented workplan

Yes	*No*	*Workplan Details*
		Inspection projections and plan
		Sample projections and plan
		Timeframe that the workplan is applicable

Notes:

Yes	No	
		Documented procedure for evaluating the workplan

Yes	*No*	*Procedure Details How*
		Program conducts periodic evaluations
		Program conducts annual evaluations
		Program evaluates alignment with program objectives and resources

Notes:

Yes	No	
		Review resources needed to accomplish the workplan and meet inspection and sample projections for the applicable workplan timeframe

Notes:

Yes	No	
		Formula to calculate the number of inspectors needed to conduct inspections

Notes:

Yes	No	
		Numerical values in the formula are verified with data tracked by the State Program

Notes:

Yes	No	
		Inspection and sample collection staff have equipment needed to conduct inspections and sample collections

Notes:

Yes	No	
		List of equipment required for inspections and sample collections

Yes	*No*	*List of equipment was*
		Established by the State program
		Maintained by the State program

Notes:

Yes	No	
		Review resources required to implement the AFRPS

Yes	*No*	*Resource review was*	*Date*
		Made concurrently with the baseline evaluation required for AFRPS Standard 9	
		Reevaluated within three years of previous evaluation	

Notes:

Assessment Completed By:

Name _____ Date _____

Appendix 8.2: Example Formula for Calculating the Number of Inspectors Required to Conduct Inspections of Feed Facilities

This appendix is an example of how to calculate the number of field staff required to conduct inspections of feed facilities. A State program may use this example to develop a formula that is suitable for the program's needs and based on data that can be verified by the program. This formula is specific to calculating the number of inspectors needed to conduct inspections of the establishment inventory according to the workplan and is not applicable to staff needs for other program areas including sample collection, response, laboratory services, or administration.

Calculating the Number of Inspectors:

1. The following data must be collected. Records must be maintained to verify the data used in the calculations.

   - Risk categorization of feed facilities (example categorization: high risk, medium risk, and low risk)
   - Number of feed facilities in each risk category
   - Percent of facilities to be inspected each year in each risk category (in percent)
   - Percent of facilities to be re-inspected each year in each risk category (in percent)
   - Average inspection time, including travel time, of feed facilities in each risk category (in hours)
   - ***Note**: The following formulas do not account for sample collections. For State programs that utilize inspectors to collect samples, the State program should consider adding additional time to the average inspection time, if appropriate, to account for sample collection.*

2. Calculate the available annual inspection time, in hours, per inspector (AIT)

   The State program should determine the average number of hours an inspector has available to conduct inspections each year after accounting for annual leave, sick leave, holidays, training, and other State program activities.

3. Calculate the number of hours required to inspect feed facilities in each risk category

   The example below utilizes three risk categories: high risk, medium risk, and low risk.

   - *For High Risk Feed Facilities:*

   [(#HR x %HRF) + (#HR x %HRRF)] x HRaIT = hHRI per year

Key	Description
#HR	Number of High Risk Facilities
%HRF	Percent of High Risk Facilities to be Inspected per Year (%)
%HRRF	Percent of High Risk Facilities to be Re-Inspected per Year (%)
HRaIT	High Risk Facility Average Inspection Time (h)
hHRI per year	Total Hours of High Risk Inspections per Year

- *For Medium Risk Feed Facilities:*

[(#MR x %MRF) + (#MR x %MRRF)] x MRaIT = hMRI per year

Key	Description
#MR	Number of Medium Risk Facilities
%MRF	Percent of Medium Risk Facilities to be Inspected per Year (%)
%MRRF	Percent of Medium Risk Facilities to be Re-Inspected per Year (%)
MRaIT	Medium Risk Facility Average Inspection Time (h)
hMRI per year	Total Hours of Medium Risk Inspections per Year (h)

- *For Low Risk Feed Facilities:*

[(#LR x %LRF) + (#LR x %LRRF)] x LRaIT = hLRI per year

Key	Description
#LR	Number of Low Risk Facilities
%LRF	Percent of Low Risk Facilities to be Inspected per Year (%)
%LRRF	Percent of Low Risk Facilities to be Re-Inspected per Year (%)
LRaIT	Low Risk Facility Average Inspection Time (h)
hLRI per year	Total Hours of Low Risk Inspections per year (h)

4. Using the data calculated in 2 and 3, calculate the number of inspectors required to ensure coverage of Program's establishment inventory.

   (hHRI per year + hMRI per year + hLRI per year) / AIT = **Number of Inspectors Needed**

Appendix 8.3: Example List of Equipment Used for Inspections and Sample Collections

Standard 8 requires a State program to develop a list of equipment needed to conduct inspections and sample collections. The list provided below is an example equipment list for inspections and sample collections. A State program may add and remove equipment from the table in developing the program's list of equipment. After the State program finalizes its list, the State program can use the chart below to record whether the equipment is assigned, available to inspectors, or not available.

Equipment	Assigned	Available	Not Available
Computer and printer			
Camera			
Cell phone			
Credentials			
Regulations, policies, and designated reference material			
Paper, pen, masking tape, and marker			
Clipboard			
Calculator			
Required forms			
Alcohol swabs and wipes			
Flashlight and holder			
Blacklight			
Light meter			
Thermometer			
Knife and scissors			
Putty knife and scraper			
Test weights			
Sampling devices (sieves, triers, scoops, or probes)			
Sampling equipment (sterile containers, bags, or swabs)			
Coolant (ice and freezer packs)			
Shipping containers			
Official seals			
Protective clothing (lab coat, gloves, and shoe covers)			
Eye protection			
Hearing protection			
Hard hat			
Safety shoes			
Respirator			
Dust mask			

Appendix 8.4: Resources for Implementation of AFRPS

This table provides an overview of a State program's evaluation of the resources needed to implement the Animal Feed Regulatory Program Standards. Based on the evaluation, indicate for each standard whether the State program has the resources needed for funding, staffing, and equipment by inserting 'Yes' or 'No' in the corresponding block. If no, please explain. Resources not related to funding, staffing, and equipment needed for implementation should be in the "Other Resources Needed" column.

Standard		Funding	Staffing	Equipment	Other resources needed
1	**Regulatory Foundation**				
2	**Training**				
3	**Inspection Program**				
4	**Auditing**				
5	**Feed-Related Illness or Death and Emergency Response**				
6	**Compliance and Enforcement**				
7	**Outreach Activities**				
8	**Planning and Resources**				
9	**Assessment and Improvement**				
10	**Laboratory Services**				
11	**Sampling Program**				

Appendix 9.1: Assessment and Improvement Plan

Instructions: This appendix, or a comparable form, must be completed for each standard with the exception of Standard 9: Assessment and Improvement.

Standard Number and Title: _____

Date Self-Assessment Worksheet Completed: _____

Subject Matter Expert(s): _____

Implementation Status

☐ Fully Met ☐ Partially Met ☐ Not Met

Instructions: For elements of the standard that are not fully met, the information listed below must be completed.

Element(s) of Standard Not Fully Met	Improvement(s) Needed to Meet Element	Task(s) to Complete Identified Improvement	Projected Completion Date for Task	Date Task Completed

Assessment Completed By:

_____ _____

Name Date

Appendix 9.2: Implementation Status of Animal Feed Regulatory Program Standards

This table provides an overview of a State program's evaluation of its implementation of the Animal Feed Regulatory Program Standards. The self-assessment worksheets and Appendix 9.1: Assessment and Improvement Plan should be used to complete this appendix.

Standard Number	Self-Assessment Completion Date	Implementation Status
1		☐ Fully Met ☐ Partially Met ☐ Not Met
2		☐ Fully Met ☐ Partially Met ☐ Not Met
3		☐ Fully Met ☐ Partially Met ☐ Not Met
4		☐ Fully Met ☐ Partially Met ☐ Not Met
5		☐ Fully Met ☐ Partially Met ☐ Not Met
6		☐ Fully Met ☐ Partially Met ☐ Not Met
7		☐ Fully Met ☐ Partially Met ☐ Not Met
8		☐ Fully Met ☐ Partially Met ☐ Not Met
9	***Not applicable***	
10		☐ Fully Met ☐ Partially Met ☐ Not Met
11		☐ Fully Met ☐ Partially Met ☐ Not Met

Evaluation Completed By:

Name _____ Date _____

Appendix 10: Self-Assessment Worksheet

Instructions: The State program should identify if they have a specified documented procedure then evaluate the procedure to determine if it includes the associated components. If the State program has the procedure and associated components check 'Yes,' if not, check 'No.'

Yes	No	
		The State program has a list of routine and non-routine analytical services

Notes:

Yes	No	
		The State program has formal agreements with laboratories outside the program that conduct routine analytical services

Notes:

Yes	No	
		The State program has a sample analysis schedule with each laboratory performing routine services

Yes	*No*	*The sample analysis schedule includes:*
		Type(s) of feed to be analyzed
		Number of samples to be collected
		Estimated time period for collection
		Type(s) of analysis to be performed

Notes:

Yes	No	
		The State program has standard procedures and a means to communicate that have been developed by the program and each laboratory performing routine services

Yes	*No*	*The procedures includes sample:*
		Submission
		Shipping
		Preservation
		Storage
		Retention
		Disposal
		Change of Custody
		Report of Analysis

Notes:

Yes	No	
		The State program has documentation for each regulatory testing laboratory that verifies it follows AAFCO QA/QC guidelines, ISO/IEC 17025-2005, or is accredited

Notes:

Assessment Completed By:

Name

Date

Appendix 11: Self-Assessment Worksheet

Program Elements	Yes/No	Specific Reference[23]	Notes
Section I. Sampling Plan			
a. Does the State program have a documented annual sampling plan?			
b. Was the sampling plan jointly developed by the State program and laboratories performing routine services?			
c. Is the sampling plan jointly amended by the State program and laboratories performing routine services?			
d. Does the sampling plan outline • The sampling priorities?			
• The sampling and analysis schedule?			
• Availability/Coordination of laboratory support?			
Section II. Sampling Procedure			
Does the State program's sampling procedure require sample collectors to			
a. Follow safety precautions on feed labels?			
b. Follow the State program's safety protocol for collecting samples?			
c. Use appropriate method and equipment to collect the sample?			
d. Seal sample to initiate chain of custody?			
e. Maintain and document sample integrity and security?			
f. Issue receipt for sample?			
g. Handle, package, and ship sample using procedures appropriate to prevent compromising condition of sample?			
h. Deliver or ship sample to the appropriate laboratory within acceptable timeframes?			
Does the State program's sampling procedure provide instructions for documenting the sample collection, including			
a. Date of the sample collection?			
b. Product identification including • Name? • Manufacturing codes? • Date codes? • Lot numbers? • Batch codes? • Expiration dates? • Other referencing manufacture identification?			
c. Description of product?			

[23] Reference the document (include section and page number) in which the program element is found.

Appendix 11: Self-Assessment Worksheet (continued)

Program Elements	Yes/No	Specific Reference	Notes
Section II. Sampling Procedure (continued)			
d. Collection information including • Method of collection? • Lot sampled? • Lot size? • Special techniques used to collect sample?			
e. Location where sample was collected?			
f. Name and address of responsible party, guarantor, possessor, or distributor?			
g. Sample type (surveillance, compliance, investigational, or regulatory)?			
h. Analysis requested, if applicable?			
i. Product labels, including customer-formula feed labels, are collected or reproduced?			
j. Receiving and distribution information?			

Assessment Completed By:

Name _____ Date _____